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Wood Preservative Pesticides: Creosote Pentachlorophenol and the Inorganic Arsenicals. Position Document 4

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This Position Document 4 contains the Environmental Protection Agency's (EPA) final decision on the Wood Preservatives Pentachlorophenol, Creosote and Inorganic Arsenicals. EPA has decided to: restrict use of these chemicals to certified applicators; require reduction of dioxin (HxCDD) in pentachlorophenol products; institute a consumer awareness program for safe handling of pressure-treated wood; and further protect workers in wood treatment plants through protective clothing and other measures. This regulatory action was taken under the authority of the Federal Insecticide, Fungicide and Rodenticide Act.

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Position Document 4

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WOOD PRESERVATIVE PESTICIDES
CREOSOTE, PENTACHLOROPHENOL, AND THE INORGANIC ARSENICALS

POSITION DOCUMENT 4

REGISTRATION DIVISION
OFFICE OF PESTICIDE PROGRAMS
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES
U.S. ENVIRONMENTAL PROTECTION AGENCY

Executive Summary

The three wood preservatives considered in this Position Document 4 are creosote, which includes creosote, coal tar and coal tar neutral oil; the inorganic arsenical compounds, which include chromated copper arsenate (CCA), ammoniacal copper arsenate, (ACA), and fluor chrome arsenic phenol (FCAP); and pentachlorophenol, including its sodium salt. These pesticides preserve wood against attack by fungi, insects, bacteria, and marine borers. Treated wood generally has a useful life at least five times longer than untreated wood.

The wood preservatives may be applied by pressure-treatment or non-pressure treatment methods. Pressure-treated wood is used for railroad ties, lumber, timber and plywood, pilings, posts, crossarms, and poles. Non-pressure uses are for poles at groundline, home and farm, and brush-on treatments of the inorganic arsenicals for cut-ends of treated wood at construction sites, sapstain control, millwork and plywood, and particleboard. For many uses, creosote, the inorganic arsenicals, and pentachlorophenol are alternatives for each other. There are several other wood preservatives as well, but these three wood preservatives are by far the most commonly used.

On October 18, 1978, the Agency published a Notice in the Federal Register initiating the Rebuttable Presumption Against Registration (RPAR) for the three major wood preservatives under the authority of the Federal Insecticide Fungicide, and Rodenticide Act (FIFRA). For creosote, the risk criteria presented in the Position Document I (PD 1)were oncogenicity and mutagenicity; for pentachlorophencol and its sodium salt they were teratogenicity and fetotoxicity; and for the inorganic arsenicals they were, onocogenicity, mutagenicity, and reproductive or fetotoxic effects.

Comments on this Notice were received and addressed in the Position Document (PD) 2/3 which was made available to the public on February 19, 1981. The Agency indicated in the PD 2/3 that pentachlorophenol also posed the additional potential risk of oncogenicity because of its hexachlorodibenzo-p-dioxin (HxCDD) and hexachlorobenzene (HCB) contaminants. Because each of the three wood preservatives are potential alternatives to each other, they were addressed together in the PD 2/3. The PD 2/3 presented the risks and benefits of use of the wood preservatives and proposed regulatory measures to reduce these risks so that benefits would exceed risks. The regulatory measures proposed in the PD 2/3 included canceling and denying registrations of spray formulations of pentachlorophenol containing less than 5% pentachlorophenol, prohibiting indoor applications of the wood preservatives, prohibiting most indoor uses of treated wood and prohibiting uses of wood preservatives likely to contaminate food, feed or drinking water. Other proposed measures were requiring use of protective clothing and equipment, such as gloves, coveralls, and respirators, requiring improved industrial hygiene practices, and classifying most formulations of the wood preservatives for use only by certified applicators. Other proposed measures included requiring closed mixing systems for powder and granular wood preservative formulations, and requiring improved treatment technologies to reduce surface residues of the wood preservatives. Finally, the Agency also recommended that under the authority of the Toxic Substances Control Act (TSCA) labeling measures be proposed for treated wood to instruct users of treated wood in proper handling and safe use procedures.

The FIFRA Scientific Advisory Panel (SAP), U.S. Department of Agriculture (USDA), industry, and other interested parties submitted written comments to the Agency on the PD 2/3. As a result of these comments, the Agency modified its PD 2/3 proposals and held a public meeting on April 14, 1983, to give interested persons an opportunity to comment on the proposed changes. All comments submitted in response to the PD 2/3 and the public meeting have been evaluated and are addressed in the final Position Document 4 (PD 4).

This PD 4 presents regulatory measures to be enforced under FIFRA to reduce potential risks to man and the environment. Most of these regulatory measures are similar to those proposed in the PD 2/3. The most significant new requirement would immediately limit the HxCDD contamination in technical pentachlorophenol and sodium pentachlorophenate to 15 ppm and would require industry to reduce this contaminant to 1 ppm or lower within 18 months. A comparison of the PD 2/3 proposals and the PD 4 final positions is summarized in the Executive Summary Table.

This PD 4 also describes a measure to require commercial wood treaters to participate in a "Consumer Awareness Program" (CAP) whereby a Consumer Information Sheet (CIS) would be distributed throughout the chain of commerce to end-users. The CIS would inform end-users of treated wood about safe use and proper handling precautions of the pesticide treated wood. If the Consumer Awareness Program is ineffective in educating the public, the Agency will initiate rulemaking under TSCA to propose that labeling material accompany the treated wood, so that end-users of the treated wood will be adequately informed about appropriate precautions to take when handling treated wood.

The final regulatory position is summarized in the Executive Summary Table and in more detail in the paragraphs which follow.

For both pressure and non-pressure treatments, the Agency will:

- Classify all three chemicals for Restricted Use only by Certified Applicators (except for brush-on treatments of the inorganic arsenicals).

- Require commercial wood treaters to participate in a Consumer Awareness Program which would require a Consumer Information Sheet (CIS) to be distributed with each shipment of pressure-treated wood throughout the chain of commerce. The CIS will instruct end-users about handling and disposal of treated wood or treated wood products. The CIS will also contain statements to reduce potential contamination of the environment by recommending against the use of treated wood in contact with food, feed, public drinking water (all 3 wood preservatives) and with drinking water for animals (pentachlorophenol and creosote). The CIS will also require that purchasers not use the wood treated with pentachlorophenol or creosote for interior use with certain exceptions and that pentachlorophenol or creosote treated wood should not be used in barns where domestic animals might lick the wood.

- Require impermeable gloves for all three chemicals in all use situations, and additional clothing and respirators in certain situations.

- Prohibit eating, drinking, smoking during application of all three chemicals.

For all products containing technical pentachlorophenol or its salts, the Agency will require registrants to:

- File an application to amend the confidential statements of formula (CSF) for products containing technical pentachlorophenol or its salts to indicate that the HxCDD contamination does not exceed 15 ppm and that 2,3,7,8-tetrachlorodibenzo-p-dioxin is below limits of detection using a gas chromatography-mass spectrophotometry method.

- File an application to amend the CSFs for products containing technical pentachlorophenol or its salts to indicate that, effective 18 months after publication of the Notice or receipt by the registrant (whichever occurs later), the HxCDD contamination does not exceed 1.0 ppm. (The method used to lower the HxCDD to 15.0 ppm or 1.0 ppm or lower must not increase the hexachlorobenzene or chlorinated dibenzofurans above the levels in products marketed at the time of publication of the FR Notice.)

- Finally, the Agency will require a teratogenicity/fetotoxicity warning on the labels for all uses of pentachlorophenol and salts of pentachlorophenol.

For Pressure Treatment Uses only, in addition to the actions listed above the Agency will require applicators to:

- Wear a respirator when opening cylinder doors or entering cylinders in pentachlorophenol and creosote treatment plants.

- Wear a respirator if arsenic air levels are unknown or exceed 10 ug/m^3 over an 8 hour period as shown by monitoring. This is consistent with the OSHA Threshold Limit Value (TLV) of 10 ug/m^3.

- Adhere to industry standards to reduce surface residues of arsenic on treated wood.

- Wear protective clothing (i.e., overalls, jackets, gloves, and boots) when entering cylinders for any wood preservative.

- Use closed systems for mixing and emptying powdered formulations of the inorganic arsenicals.
- Use protective clothing and a respirator when mixing and emptying prilled or flaked formulations of pentachlorophenol; closed systems must be used after a 3 year "phase-in" period.

In addition to the requirements listed above for Non-Pressure Treatment Uses, the Agency has determined that registrants must meet further requirements as listed below for specific non-pressure use situations:

- Groundline treatment of poles - protective clothing.
- Home and farm uses of pentachlorophenol and creosote - restrict use to certified applicators, protective clothing;
- Brush-on (arsenicals) - commercial construction use only; protective clothing.
- Sapstain Control (i.e., pentachlorophenol salts applied to prevent staining of wood by black mold) - protective clothing when entering vats; respirator and protective clothing for spray applications if there is a visible mist; protective clothing and a respirator when emptying and mixing powdered formulations of sodium pentachlorophenate, but closed systems must be used after a 3 year "phase-in" period.
- Millwork, Plywood, Particleboard - protective clothing for entering vats; respirator and protective clothing for spray applications if there is a mist; protective clothing and a respirator when emptying and mixing prilled or flaked formulations of pentachlorophenol, but closed systems must be used after a 3 year "phase-in" period.

In an action separate from this PD 4, the registrants of technical pentachlorophenol and salts of pentachlorophenol products of will be required to submit the following to maintain existing registrations pursuant to FIFRA Section 3(c)(2)(B):

- A description of the starting materials, manufacturing process and reaction conditions including any steps to reduce HxCDD.
- Information on product identity relative to identification of ingredients, statement of composition and a discussion of the formation of impurities.

- Data on the analysis and certification of product ingredients relative to preliminary analysis, certification of limits, and analytical methods for the enforcement of limits. An analytical method employing combined gas chromatography and mass spectrophotometry is acceptable (e.g., Buser and Bosshardt, 1976).

- HxCDD analyses every three months, the first analysis to be submitted within 90 days.

- A description of any changes in the manufacturing process used to lower HxCDD to 15 ppm and/or to 1 ppm. The methods used to lower HxCDD must not increase the dibenzofurans or hexachlorobenzene (HCB) contaminants.

- Information on the technical feasibility and costs of reducting the HxCDD even further than the 1.0 ppm upper limit.

In addition the Agency will require registrants to submit the following data via Section 3(c)(2)(B) of FIFRA:

- CORT (Chronic feeding, Oncogenicity, Reproductive effects, and Teratogenicity) data for chemical alternatives to the three wood preservatives.

- Data on the effectiveness of protection afforded by specific protective clothing materials for creosote and the inorganic arsenicals.

- An epidemiology study and air monitoring and dermal exposure data for creosote workers at creosote wood treatment plants.

- Teratogenicity/fetotoxicity studies on inorganic arsenic to enable the Agency to calculate a NOEL (No Observable Effect Level).

- Exposure data on spray applications of pentachlorophenol for home and farm use.

The Agency has determined that there will be no unreasonable adverse effects posed to man or the environment if registrants amend their applications for registration of the three wood preservatives to include these requirements.

EXECUTIVE SUMMARY TABLE

Comparison of PD 2/3 Proposals with Agency's Final Position (PD 4) for the Wood Preservatives

Use	PD 2/3 Proposal	PD 4 Final Position
1. All Uses of		
a. Penta* and Penta salts	Not proposed	- Immediate upper limit of 15 ppm HxCDD; TCDD below limits of detection
		- In 18 months, 1ppm HxCDD upper limit
	- Not Proposed	- Teratogenicity/fetotoxicity label warning.
b. All Chemicals	- Disposal of protective clothing	- Disposal of protective clothing and unused formulations
	- Statements regarding personal hygiene during and after application	- Statements regarding personal hygiene during and after application
2. Pressure-Treatment		
a. All three chemicals	- Recommended TSCA labeling of wood to educate purchasers of treated wood about proper use and handling procedures.***	- FIFRA Mandatory Consumer Awareness Program - distribution of CIS** to educate purchasers of treated wood about proper use and handling procedures.
	- Restrict Use	- Restrict Use
	- Gloves and protective clothing	- Gloves and protective clothing

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* Penta = pentachlorophenol.

** CIS = Consumer Information Sheet, which will accompanying each shipment of pressure-treated wood.

*** Also recommended for non-pressure treated wood. The PD 4 requires the mandatory consumer Awareness Program only for pressure-treated wood; exposure and risk are estimated to be minimal for non-pressure treated wood, such that a Consumer Awareness Program is nt required for non-pressure wood treaters.

Use	PD 2/3 Proposal	PD 4 Final Position
	- Respirators when entering cylinders	- Respirators when entering cylinders (penta and creosote)
	- Respirators when opening cylinder doors (penta and creosote	- Respirators when opening cylinder doors (penta and creosote)
	- Dust masks (Inorganic arsenicals)	- Respirators if inorganic arsenic in air is unknown or exceeds 10 ug/m^3 averaged over 8 hours
	- Closed mixing and emptying system (powder inorganic arsenicals; dry formulations of penta and Na penta)	- Closed mixing and emptying system immediately for arsenic and within 3 years for dry penta and Na penta formulations
	- "clean wood" standards (inorganic arsenicals)	- "Clean wood" standards (inorganic arsenicals)
	- Prohibitions on applying formulations to wood intended for use in interiors (with certain exceptions) or for use in contact with food, feed, or drinking water	- Prohibitions on applying formulations to wood intended for use in interiors (with certain exceptions) or for use in contact with food, feed, or drinking water

Use	PD 2/3 Proposal	PD 4 Final Position
3. Groundline treatment of poles (penta and creosote)	- Restrict Use	- Restrict Use
	- Protective clothing	- Protective Clothing
4. Home and Farm (including repair of railroad ties) (penta and creosote)	- Restrict use of all creosote products	- Restrict use of all creosote products
	- Restrict use of pentachlorophenol products containing more than 5% pentachlorophenol; Cancel spray pentachlorophenol products of less than 5% pentachlorophenol	- Restrict use of all pentachlorophenol products
	- Prohibit application indoors	- Prohibit application indoors
	- Prohibit application to wood intended for use in interiors (with certain exceptions) or for use in contact with food, feed, or drinking water	- Prohibit application to wood intended for use in interiors (with certain exceptions) or for use in contact with food, feed, or drinking water
		- Additional precautionary statements regarding handling and disposal of treated wood

Use	PD 2/3 Proposal	PD 4 Final Position
5. Brush-on treatments of the inorganic arsenicals	- Restricted Use	- Unclassified Use
	- Protective clothing	- Protective clothing
	- Prohibit application to wood intended for use in interiors (with certain exceptions) or in contact with food, feed, or drinking water	- For commercial construction use only; for application to the cut ends of wood pressure-treated with inorganic arsenicals; not for household use.
6. Sapstain control (salts of pentachlorophenol)	- Restricted Use	- Restricted Use
	- Protective clothing; respirator when entering vats and during spray operations	- Protective clothing; respirator when entering vats and during spray operations only if there is a visible mist and the applicator is near the automated spray apparatus.
	- Closed mixing and emptying systems for powdered Na penta	- Closed mixing and emptying systems for powdered Na penta within 3 years
	- Prohibit application to wood intended for use in contact with food, feed or water	- No regulation (exposure not expected)

Use	PD 2/3 Proposal	PD 4 Final Position
7. Millwork, plywood, particle board (penta)	- Restrict use	- Restrict use
	- Protective clothing; respirator when entering vats and during spray operations	- Protective clothing; respirator when entering vats and during spray operations only if there is a visible mist and the applicator is near the automated spray apparatus.
	- Closed mixing and emptying systems for dry penta formulations	- Closed mixing and emptying systems for dry penta formulations within 3 years
	- Prohibit the application to wood intended for use in interiors (with certain exceptions) or for use in contact with food, feed, or water	- No regulation for millwork, plywood, particleboard (minimal exposure)
		- Prohibit application to logs intended for log homes

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I. INTRODUCTION

A. Historical Background

On October 18, 1978, the U.S. Environmental Protection Agency published in the FEDERAL REGISTER notices of rebuttable presumption against registration (RPAR) for pesticide products containing coal tar, creosote and coal tar neutral oil (these three products will be referred to as "creosote"), inorganic arsenicals, and pentachlorophenol, including its sodium salts (43 FR 48154, 48267, and 48443, respectively). For creosote, the rebuttable presumption was based on oncogenicity and mutagenicity. For the inorganic arsenical pesticides, the rebuttable presumption was based on oncogenicity, mutagenicity and reproductive or fetotoxic effects. For pentachlorophenol, the rebuttable presumption was based on teratogenicity and fetotoxicity.

On February 19, 1981 (46 FR 13020), the Agency published a preliminary notice of determination concluding the RPAR for the wood preservative uses of creosote, the inorganic arsenicals and pentachlorophenol (which will be referred to as the wood preservative chemicals). In that preliminary notice and the supporting Position Document (PD) 2/3, the Agency determined that the wood preservative chemicals continued to exceed the risk criteria which were the bases for the RPARs. The Agency also determined that the use of pentachlorophenol and its sodium salt pose the risk of oncogenicity because of the presence of the contaminants hexachlorodibenzo-p-dioxin (HxCDD) and hexachlorobenzene (HCB), which also have the potential to produce teratogenic/fetotoxic effects. To reduce the risks from the use of the wood preservative chemicals, the Agency proposed to modify the terms and conditions of registration as follows:

- Cancel spray pentachlorophenol products available for retail sale in concentrations of 5% or less.
- Classify some products for restricted use.
- Require protective clothing and equipment (e.g., respirators).
- Prohibit eating, drinking and smoking while applying wood preservatives.
- Require proper care and disposal of work clothing and equipment
- Require a closed mixing and a closed emptying system for all prilled (granular) formulations of pentachlorophenol, powder and prilled (granular) formulations of sodium pentachlorophenate and the powder formulations of the inorganic arsenicals.
- Prohibit indoor application of the wood preservatives.
- Prohibit the use of pesticide-treated wood indoors, except for a few low exposure uses;

- Prohibit application of the wood preservative pesticides in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed or drinking and irrigation water.

- Require control technologies to reduce arsenic surface residues on the treated wood.

In light of the high economic benefits resulting from the use of the wood preservative chemicals, the Agency determined in the PD 2/3 that the use of the wood preservative chemicals in accordance with these modifications would satisfy the statutory standard for continued registration.

In addition, the Agency recommended that regulatory measures be proposed under the Toxic Substances Control Act (TSCA) for the use of treated wood. The proposed TSCA rule would have included a requirement that labeling to explain use, handling, and disposal precautions to users accompany the treated wood products. Among the recommended labeling measures were:

- The use of gloves when handling treated wood.

- The use of a dust mask and coveralls when sawing treated wood.

- The prohibition of interior uses of treated wood (with certain exceptions).

- The prohibition of uses which may result in direct exposure to livestock or the contamination of food, feed, or water.

- The prohibition of the burning of treated wood.

The Agency submitted its preliminary determinations to the FIFRA Scientific Advisory Panel (SAP) and the U.S. Department of Agriculture (USDA) for review pursuant to sections 6(b) and 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency also solicited comments from the registrants and any other interested parties. After reviewing the comments from the SAP, the U.S. Department of Agriculture, the registrants and other interested parties, the Agency modified the proposed decision announced in the Preliminary Notice of Determination. The Agency held a public meeting on April 14, 1983, to give interested persons the opportunity to comment on changes to the decision proposed in the Preliminary Notice. The Agency carefully considered the comments submitted in response to this meeting in the development of the final decision; the comments are discussed in detail in this document.

This position document discusses new information received since the publication of the PD 2/3 and comments on the PD 2/3 from the SAP, USDA, and other interested parties; it describes the changes in exposure and risk resulting from the new information; and it provides the Agency's final regulatory position and the rationale and bases for that position.

Section I is this introduction. Section II discusses new risk, exposure and benefit information received by the Agency since the publication of the PD 2/3. Sections III, IV, and V summarize the SAP, USDA and other public comments, and the Agency's responses to those comments. Each of the Sections VI.A through VI.H describes a specific exposure situation of concern, the PD 2/3 proposal to reduce the exposure and risk, comments and/or new information, and the Agency's final regulatory position and the rationale and bases for that position.

Section VII discusses the Consumer Awareness Program in which commercial wood treaters must participate to inform end-users of treated wood about safe handling practices and uses of the pesticide treated wood. Section VII.C contains a sample Consumer Information Sheet (CIS) which would be distributed with each shipment of pressure-treated wood throughout the chain of commerce and which would be available to the end-user or purchaser of the treated wood. Section VIII summarizes the Agency's final regulatory position listing the required modifications to the terms and conditions of registration for the three wood preservatives. Section VIII also summarizes additional data requirements which will be imposed on the registrants by the Agency to continue in effect existing registrations of the wood preservatives. The registrants will be notified of the additional data to be submitted by them in an action separate from this PD 4 pursuant to Section 3(c)(2)(B) of FIFRA.

The worker protection requirements specified in this document are established pursuant to FIFRA which provides no means of regulating occupational safety and health hazards except insofar as they are directly associated with use of a registered pesticide. EPA has made no attempt to regulate any workplace hazard except those associated with the use of pesticide products containing creosote, pentachlorophenol (and its salts) and the inorganic arsenicals as wood preservatives. EPA in developing these worker protection requirements has only considered the hazards directly attributed to the use of these pesticides.

Appendix A presents a comparison of the PD 2/3 proposals with the Agency's final regulatory position. Appendix B is a table comparing the risks with and without protective measures as calculated in the PD 2/3 with the risks with and without protective measures recalculated based on new data and other information received since publication of the PD 2/3. Appendix C is a table comparing the recalculated exposures used in this position document to calculate new risks for the three wood preservatives in various use situations, with and without protective measures. Appendices D and E contain the SAP and USDA comments in their entirety.

B. Legal Background

To obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), as amended, an applicant for registration must show that the pesticide satisfies the statutory standard for registration. That standard requires, among other things, that the pesticide perform its intended function without causing "unreasonable adverse effects on the environment." FIFRA § 3(c)(5).

The term "unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" FIFRA § 2(bb). To register a pesticide, the Administrator must find that the benefits of each use of the pesticide exceed the risks of use, when the pesticide is used in accordance with commonly recognized practice and in compliance with the terms and conditions of registration.

The burden of proving that a pesticide satisfies the registration standard is on the proponents of registration and continues as long as the registration remains in effect. Under section 6 of FIFRA, the Administrator may cancel the registration of a pesticide or modify the terms and conditions of registration whenever it is determined that the pesticide causes unreasonable adverse effects on the environment. The Agency created the RPAR process to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and to provide an informal procedure to gather and evaluate information about the risks and benefits of these uses.

The regulations governing the RPAR process are set forth in 40 CFR 162.11. Among other things, this section provides that a rebuttable presumption against registration shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations. The Agency announces the commencement of the RPAR process by publishing a notice in the Federal Register. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to humans or the environment with regard to the adverse effects in question. In addition to submitting evidence to rebut the risk presumption, respondents may submit evidence as to whether the economic, social and environmental benefits of the use of the pesticide outweigh the risks of use.

In determining whether the use of a pesticide poses risks which are greater than the benefits, the Agency considers possible changes to the terms and conditions of registration which can reduce risks, and the impacts of such modifications on the benefits of use. If the Agency determines that such changes sufficiently reduce risks to the level where the benefits outweigh the risks, it may conclude the RPAR process. The Agency announces this type of conclusion to an RPAR review by publication of a Notice of Determination in the Federal Register. That Notice states and explains the rationale for the Agency's regulatory position, provides that the registrant may avoid cancellation by implementing the modifications to the terms and conditions of registration set forth in the Notice, and sets forth the hearing rights of the affected parties.

II. UPDATED RISK AND BENEFIT INFORMATION

Since the publication of the PD 2/3, the Agency has received additional information from the United States Department of Agriculture (USDA), the wood preserving industry, and published articles on risk and exposure to the wood preservatives.

As a result of the new information received and evaluated by the Agency, the exposure and risk estimates for certain uses of the wood preservative chemicals were recalculated. In some instances the change in risk estimates caused the Agency to modify the regulatory proposals set forth in the PD 2/3. The changes in regulatory position and the reasons for these changes are discussed in this document in Sections VI through VII.

This section of the document describes the new information and presents the Agency's rationale for modifying or not modifying the exposure and risk assumptions as stated in the PD 2/3.

A. Risk Information

1. Inorganic Arsenicals

a. Inhalation Risk Model

PD 2/3 Risk Model: The risk model (CAG, 1978) used in PD 2/3 (p. 215) for inhalation exposure to inorganic arsenicals was based on three epidemiological studies, namely, two of copper smelter workers in Anaconda, Montana (Lee and Fraumeni, 1969), and Tacoma, Washington (Pinto et a.l, 1977), and one of a pesticide manufacturing plant (Ott, et al., 1974). These studies analyzed the relationship between mortality and exposure to arsenic. The risk equation used in the PD 2/3 to estimate potential risks from inhalation exposure was

$$P = 1-e^{-2.95x10^{-3}X}$$

where X is the arsenic exposure expressed in ug/m^3 (PD 2/3, p. 215). The airborne arsenic in the smelters was in the trivalent form while the airborne arsenic in the pesticide manufacturing plant was in the pentavalent form (PD 2/3, p. 108).

PD 4 Risk Model: New information received since the PD 2/3 was published was evaluated by the Agency and used to reestimate the potential inhalation risk due to arsenic exposure. A summary of the data and the development of the risk equation used to estimate the risks presented in this document are contained in the paragraphs which follow. The Agency's Carcinogen Assessment Group (CAG) evaluated the new data in preparing a document for the Office of Health and Environmental Assessment (OHEA) on arsenic risk assessment (U.S. EPA, June 1983).

Several studies (Higgins, et al., 1982; Enterline and March, 1983; and Lee-Feldstein, 1982) were used by the CAG in revising its 1980 (PD 2/3) risk assessment for inhalation exposure (U.S. EPA, June 1983). In addition, new analyses by Brown and Chu from the National Cancer Institute (NCI) were also used in the risk revisions (Brown and Chu, 1983a and 1983b). A detailed discussion of the inhalation risk analysis for arsenic is presented in Chapter 5 of the OHEA (U.S. EPA, June 1983) document on arsenic.

The Enterline and Marsh (1982) study included 2802 men working at a Tacoma, Washington, smelter for a year or more between 1940 and 1964. Individual exposures to arsenic were estimated using work histories and measurements of arsenic in urine. The study cites 104 deaths due to respiratory cancer. This study is summarized on pp. 5-120 to 5-123 of the OHEA document (U.S. EPA, June 1983).

The Lee-Feldstein (1982) study surveyed 8047 smelter workers in Anaconda, Montana. This large study followed mortality for 39 years and included observations of a considerable number of respiratory cancer deaths. Enough detail of exposure levels and work histories was available for estimations of individual exposures and dose-response. This study is summarized in the OHEA document (U.S. EPA, June 1983, pp. 5-94 to 5-99)

The Higgins et al. (1982) study contains additional data on 1800 men from the Anaconda smelter. Cumulative exposures were estimated and information on smoking habits was obtained for most of the cohorts. This study is summarized in the OHEA document (U.S. EPA June 1983, pp. 5-105 to 5-107).

Brown and Chu (1983a, b, and c) applied the multi-stage theory of carcinogenesis to the Anaconda smelter studies, taking into account exposure rate, durations of exposure, age at initial exposure and time since cessation of exposure. Their analysis is described in the OHEA document (U.S. EPA, June 1983, pp. 5-110 to 5-119).

The inhalation oncogenic risk of arsenic is based soley on the epidemiological studies by Higgins et al., Lee-Feldstein, and Enterline and Marsh, and the series of analysis for NCI by Brown and Chu. The Agency (U.S. EPA, 1983) esimated unit risk per ug/m^3 ranging from 1.25×10^{-3} $(ug/m^3)^{-1}$ to 7.60×10^{-3} $(ug/m^3)^{-1}$ using linear models. Taking a geometric mean, the CAG's usual statistical procedure, the final unit risk was estimated to be 4.209×10^{-3} $(ug/m^3)^{-1}$.

To estimate inhalation risk, the equation

$$P = 1-e^{-4.29x10^{-3} X}$$

was derived (McGaughy, April 14, 1984) where P is the lifetime cancer risk based on a lifetime continous exposure and where X is the continous exposure in ug/m^3. The equation is based on a linear non-threshold risk model which assumes that the age-specific rate increases proportionally to the cumulative exposure experienced up to that point in time. As a result, partial lifetime exposures of equal level and duration would have a different effect depending upon when they occurred during a lifespan (McGaughy, April 14, 1984). For an individual exposed from age 30 to age 60, the risk equation is approximately

$$(1) \qquad P \approx 2.73W$$

where W is the exposure in mg/kg working day (McGaughy, April 14, 1984). The assumptions made are that the median lifespan is 76.2 years, a 60 kg applicator while working breathes $10m^3$ of air per day for 240 days per year for 30 years, and the applicator was exposed to arsenic from age 30 to age 60. Exposure from age 18 to 48 or 40 to 70 would result in potential risk estimates that are 38% higher or 32% lower, respectively (McGaughy, April 14, 1984). The potential risk estimates presented throughout this document for inhalation exposure to the inorganic arsenicals in arsenic treatment plants were calculated using equation (1) above.

However, for estimating risks to residents (with everyday exposure at $10m^{-3}$ per day) in homes constructed with All-Weather-Wood-Foundations (AWWF) made from arsenic pressure-treated wood, the risk equation becomes

$$P \approx 2.73\left(\frac{70}{30} \times \frac{365}{240}\right)W \approx 9.7W$$

where W is expressed in mg/kg/day assuming a daily exposure over an average lifetime of 70 years (McGaughy, April 14, 1984). (One home out of 50 is constructed with AWWF's.)

For estimating risk from inhalation absorption for those who saw or fabricate structures made out of arsenic-treated wood, the "unit risk" is adjusted by a factor of $\frac{1}{0.3}$ in order to reflect "absorbed dose" (McGaughy, April 14, 1984). The OHEA document (p. 2-22) states that 30% of the arsenic would be absorbed when inhaled as arsenic trioxide in the air in copper smelters. Thus, the inhalation risk equation for sawing (handling/fabricating) arsenic treated wood is

$$P \approx \frac{2.73}{0.3}W \approx 9.1W$$

where W is exposure to arsenic-laden sawdust expressed as mg/kg/working day reflecting absorbed dose (McGaughy, April 14, 1984). The inhalation risk estimates for arsenic presented throughout this position document (PD 4) were calculated using the above equations appropriate for the various use situations.

OHEA (U.S. EPA, 1983) states that the linear non-threshold model used to estimate arsenic inhalation risk was adopted as the primary basis for risk extrapolation at low levels of exposure because, although the scientific basis is limited, it is the best of any of the current mathematical extrapolation models. However, OHEA (U.S. EPA, 1983, p. 5-88) also states that the imprecision of presently available technology for estimating cancer risks to humans at low levels of arsenic exposure should be recognized. The linear extrapolation model used here provides a rough but plausible estimate of the upper limit of risk: that is, with this model it is not likely that the true risk would be much more than the estimated risk, but it could be considerably lower (U.S. EPA, 1983).

Therefore, the potential inhalation risk estimates presented throughout this PD 4 should be viewed as upper-limit estimates and not as accurate representations of true cancer risks.

The exposures to inorganic arsenic for various use situations are contained in Appendix C of this position document. The estimated risks to inorganic arsenic are summarized in Appendix B and are compared to those calculated for the PD 2/3.

b. Dermal/Oral Risk Model

In the PD 2/3, the Agency used a risk model for dermal and oral exposure to arsenic based on an epidemiologic study of skin cancer in more than 40,000 people in a section of Taiwan with high arsenic concentrations in the well water (PD 2/3, p. 216). The Taiwan well water was predominantly pentavalent arsenic (80% pentavalent and 20% trivalent) (Irgolic, 1982).

The risk equation used in the PD 2/3 (p. 216) to estimate potential oncogenic risks from dermal and oral exposure (gastro-intestinal absorption) was

$$\text{Risk} = \frac{2.41423 \times C}{2.41423 \times C + 6.02793}$$

where C is the concentration of arsenic (mg/liter) in drinking water. Since the PD 2/3 was published, the Agency received new information on exposure to arsenic in drinking water including submissions from Koppers (#72:30000/28C).

These studies are summarized in Chapter 5 of the OHEA document (U.S. EPA, 1983) on arsenic. The Agency has concluded (U.S. EPA, 1983) that the best data available for the risk assessment for oral ingestion of arsenic remains the study of skin cancer from exposure to arsenic in the Taiwan well water (PD 2/3, p. 104) as reported by Tseng et al. (1968).

Using a Weibull dose-response model, incorporating both dose and time where dose is linear and where time is raised to the power of 3.853, the CAG derived a risk equation based on the data from Tseng et al. (1968) to estimate the potential risks of skin cancer from oral (gastro-intestinal) or dermal exposure to arsenic. The development of this model is presented in the OHEA (U.S. EPA, 1983) document in Chapter 5 (pp. 5-136 to 5-143). This method of risk estimation provides an excellent fit to the data, as evidenced by the dose-response curves (U.S. EPA, 1983, p. 5-142). It was assumed that the probability of contracting skin cancer was related to age and concentration of arsenic in ppm. The incidence rates are age-specific and are linearly related to dose. The prevalence rates were lower for younger ages and lower arsenic concentrations than for older ages and higher arsenic concentrations (U.S. EPA, 1983, p. 5-138). To obtain a unit risk estimate, lifetime risk was assumed to be approximately equal to the risk calculated for the median lifespan (76.2 years) in the absence of competing risk (U.S. EPA, 1983, p. 5-140). The risk equation for skin cancer derived for low oral exposure to arsenic is

$$P = 0.430\ X$$

where X is the exposure in mg/liter or ppm in the water (U.S. EPA, 1983, p. 5-141).

For a "working lifetime" of 30 years, it is desirable to express exposure in mg/kg/working day. For this purpose, the risk equation for skin cancer due to ingestion becomes

$$P = 3.64\ W$$

where W is the arsenic exposure from ingestion expressed in mg/kg/working day, assuming a 60 kg person drinks 2 liters of water a day and works 240 days per year for 30 years over an average lifetime of 70 years (McGaughy, April 14, 1984). In calculating the slope in units of mg/kg/day absorbed dose, it is also assumed that 100% of the arsenic in the water is absorbed through the gut (U.S. EPA, 1983, p. 5-141). The above equation (P =3.64 W) was also used to estimate the skin cancer risk from dermal exposure to arsenic for the activities of bag emptying, mixing solutions, handling freshly treated wood, "brushing-on" arsenic to the cut ends of treated wood and gastrointestinal exposure while sawing or fabricating with arsenic treated wood (McGaughy, April 14, 1984).

For exposure in flooded basements in homes with All-Weather-Wood-Foundations made from arsenic pressure treated wood, the unit risk factor is decreased by a factor of

$$\frac{1}{240 \times 30}$$

because it is assumed that there is a once in a lifetime exposure. Thus, for risk from dermal exposure to flooded basements, the risk equation is

$$P = 3.64 \left(\frac{1}{240 \times 30}\right) W$$

where W is the exposure in mg/kg/day (McGaughy, April 14, 1984).

For similar exposure estimates, the new model results in risk estimates which are slightly higher (by less than a factor of 2) than the risk estimates calculated using the model described in the PD 2/3.

The estimated dermal and oral risks estimated by the Agency for inorganic arsenic were calculated using the above equations. The estimated cancer risks for inhalation, dermal, and gastrointestinal exposure to arsenic are summarized in Appendix B in this position document and are compared to those calculated for the PD 2/3.

The PD 2/3 in some instances added the estimated risks for skin cancer and the estimated risks for respiratory cancer to present a "total" risk for arsenic. However, the Agency has determined that adding these two risks together is improper (Bayard, June 11, 1984). Exposure to arsenic taken orally has been shown to cause skin cancer in humans. Exposure to arsenic by inhalation has been shown to cause respiratory cancer in humans. The potential risk of skin cancer is separate and distinct from the potential risk of respiratory cancer. Therefore, where the risks have been recalculated for this PD 4, the potential dermal risk will not be added to the potential respiratory risk.

2. Pentachlorophenol

a. Multi-stage Model for Estimating Oncogenic Risks

The pentachlorophenol risk estimates for oncogenicity presented in this document vary slightly from the estimates derived in the PD 2/3, partly because the Agency has refined its oncogenic risk assessment method to use the "multi-stage model" rather than the "one-hit" model. For similar exposure estimates, the estimated oncogenic risks for pentachlorophenol derived by this revised methodology fall essentially in the same range as the PD 2/3 estimates. A comparison of the PD 2/3 risk estimates with the recalculated risk estimates is presented in Appendix B of this document.

The Agency described the rationale for using the multi-stage model instead of the one-hit model in the "Water Quality Criteria Document" published in the Federal Register, November 28, 1980 [45 FR 79318]. The multi-stage model is more appropriate based on mathematical, theoretical, and biological grounds, as summarized in the Appendix of that document. The "one-hit" model can be considered the first stage of the multi-stage model. The multi-stage model reduces to the one-hit model when there is only a control group and one active dose level. Most oncogenic studies include two or three active doses and thus the dose-response relationship is frequently more complex than suggested by the "one-hit" model (Litt, Feb. 22, 1984).

b. Reevaluation of the HxCDD Bioassay

In the PD 2/3, the Agency based its oncogenic risk analysis for the HxCDD contamination in pentachlorophenol on a chronic feeding study performed by the National Cancer Institute (NCI, 1980) using 1,2,3,6,7,8- and 1,2,3,7,8,9-HxCDD. The study showed an increased incidence in combined benign and malignant liver tumors in male and female rats and mice. The "one-hit" model was used to estimate carcinogenic potency. The slope derived from the female rat data was used to estimate risk to humans, as the female rat appeared to be more sensitive than the male rat or male and female mouse (PD 2/3, p. 303).

AWPI (78:30000/28c) commented that "...EPA has improperly relied on the NCI gavage bioassay..." and submitted a report by Robert A. Squire Associates, Inc. (1983) in support of this statement. Squire Associates (1983) reviewed the NCI (1980) study and, based on Dr. Squire's histopathological evaluations, reported lower incidences of neoplastic nodules and carcinomas in high dose female rats than the incidences reported by NCI (1980).

At the request of EPA, the National Toxicology Program (NTP) recently reviewed the histopathology slides to reexamine the lesions in the liver tissues of the female rats. NTP (Hildebrandt, 1983) concluded that HxCDD administered to female rats causes a toxic hepatitis and an increase in the incidence of neoplastic nodules. The toxicity effects were characterized by cytomegalia, karyomegaly, bile duct proliferation, and varying degrees of cytoplasmic vacuolization (fatty change). In determining the incidence of neoplastic nodules, Dr. Hildebrandt found that although the cells in neoplastic nodules were often vary similar to foci of cellular alteration, two differentiating features could be used; a) the degree of compressing adjacent tissue (sometimes bulging from the surface), and b) perhaps more importantly the degree of bile duct proliferation within the focus of proliferating cells. A nodule (focus) of proliferating cells compressing adjacent tissue and not containing bile ducts was diagnosed as a neoplastic nodule. A similar focus of cells that contained small bile ducts and/or small proliferating bile ducts was diagnosed as a focus of cellular alteration.

The nodules, or foci which Dr. Hildebrandt called neoplastic nodules, were either devoid of bile ducts, contained a bile duct at the periphery which was interpreted as entrapment, or had only a hint of bile duct proliferation in one small region of the nodule. Dr. Hildebrandt stated that there is some subjectivity in the criteria he used to determine the number of neoplastic nodules in the liver tissues. For example, a few neoplastic nodules would have been diagnosed as foci of cellular alterations if a reviewer was of the opinion that neoplastic nodules have no bile ducts whatsoever.

Dr. Hildebrandt found that two livers had a lesion that was compatible with hepatocellular carcinoma.

The incidences of neoplastic nodules and carcinomas reported by Dr. Hildebrandt may be compared with the findings by NCI (1980) and Squire Associates (1983) as summarized in Table 1.

Table 1

Summary of Incidences of Neoplastic Nodules and Carcinomas in Livers of Female Rats

	Neoplastic Nodules			Carcinomas		
Dose (ug/kg/wk)	Low 1.25	Mid 2.5	High 5.0	Low 1.25	Mid 2.5	High 5.0
NCI, 1980	10/50	12/50	30/50	0/50	0/50	4/50
Squire Associates, 1983	4/50	7/50	7/50	0/50	0/50	0/50

The NTP reevaluation (Hildebrandt, 1983) shows incidences of liver tumors in the range of 50% less than that of the original 1980 analysis (30 vs. 16 neoplastic nodules and 2 vs. 4 hepatocellular carcinomas at the highest dose).

The Agency's Carcinogen Assessment Group (CAG) evaluated and accepted the findings of NTP (Hildebrandt, 1983) and used those data of incidences of neoplastic nodules and carcinomas in female rats as part of the assessment of the carcinogenic potency of HxCDD.

Other data which were used were contained in the orginal report of the NCI (1980) bioassay and include incidences of tumors for male rats, male mice, and female mice. These data and the data from the NTP reevaluation (Hildebrandt, 1983) are presented in Tables 2 and 3.

Dr. McGaughy of CAG (April 24, 1984) summarized and evaluated the results of the bioassay. He stated that the bioassay showed positive results for male and female rats (combined liver neoplastic nodules or hepatocellular carcinomas) with the greater response in the females. In the females, carcinomas appeared only in the high-dose group, with a significant dose-response trend for both neoplastic nodules and nodules and carcinomas combined. In the male rats, there was also a trend for neoplastic nodules and carcinomas combined, but this was only marginally significant. These results are presented in Table 2, which includes the recent NTP reevaluation of the female rat liver slides. The review shows responses in the range of 50% less than that of the original analysis. The responses for neoplastic nodules and combined nodules and carcinomas are statistically significant.

In female mice, there was a dose-related trend in hepatocellular carcinomas, but only the combined adenomas and carcinomas were significant. In male mice, there was a minor trend in hepatocellular adenomas, but no increase, statistical or otherwise, in hepatocellular carcinomas (Table 3).

Although no statistically significant increase in carcinomas occurred in mice or rats of either sex, when neoplastic nodules in the rats and hepatocellular adenomas in the mice were included in the data, the results became significant for all groups. The neoplastic nodules in the rats are viewed as evidence of a progression response for cancer development; hepatocellular adenomas in mice are interpreted as indications of potential cancer, though the adenomas may be reversible.

In order to estimate the carcinogenic potency of HxCDD, these combined results were then fitted to the multistage model for all four groups. As shown in Tables 2 and 3, the 95% upper-limit unit risk estimates are:

Rat - male $q_1^* = 0.59\ (\mathrm{ug/kg/day})^{-1}$
female $q_1^* = 3.5\ (\mathrm{ug/kg/day})^{-1}$

Mouse - male $q_1^* = 11.0\ (\mathrm{ug/kg/day})^{-1}$
female $q_1^* = 2.9\ (\mathrm{ug/kg/day})^{-1}$

The Agency's usual procedure is to use the most sensitive sex-species for unit risk (McGaughy, April 24, 1984). Under that procedure, which for estimating the upper limit is based on the linearized multistage model with sur-

The Agency's usual procedure is to use the most sensitive sex-species for unit risk (McGaughy, April 24, 1984). Under that procedure, which for estimating the upper limit is based on the linearized multistage model with surface area correction for animal-to-man extrapolation, the male mouse data yielding a

$$q_1^* = 11.0\ (\mathrm{ug/kg/day})^{-1}$$

would be selected to provide the upper-limit estimate of potency. However, as examination of Tables 2 and 3 ahows, there are several reasons to give weight to the female rat data base also. These are:

a. Low spontaneous (control) rates in the rat versus the male mouse liver.

b. Statistically significant increases in both the mid and high level dose groups versus control for the female rat; the male mouse response was significant only at the high dose.

c. A more distinct dose response trend in the female rat versus the male mouse.

d. The only hepatocellular carcinomas in the female rat were in the high dose group. There were none in 148 control animals. By comparison, the male mouse showed no clear trend in carcinomas.

Finally, for TCDD the female rat (different strain) has been shown to be more sensitive than the mouse. Based on the above qualifications, the Agency has decided to modify its procedure slightly and to take the geometric mean of the 95% upper-limit estimates from the male mouse and the female rat. The final estimate (McGaughy, April 24, 1984) is

$$q_1^* = (3.5 \times 11.0)^{1/2} = 6.2\ (\mathrm{ug/kg/day})^{-1}$$

Table 2. HxCDD (Gavage) BIOASSAY (NCI, 1980): OSBORNE-MENDEL RATS (2 years)-INCIDENCES OF NEOPLASTIC NODULES AND HEPATOCELLULAR CARCINOMAS

Tumor	Vehicle Control	Untreated Control	Low-Dose 1.25	Mid-Dose 2.5	High-Dose 5	Estimates[a] of q_1^* $(ug/kg/day)^{-1}$
MALE (700g)[b]						
Number of animals examined	74	75	49	50	48	-------------
Hepatocellular carcinoma (HC)	0	0	0	0	1(2%)	-------------
Neoplastic nodule (NN)	0	2(3%)	0	1(2%)	3(6%)	5.6×10^{-1}
HC + NN combined	0	2(3%)	0	1(2%)	4(8%)[c]	5.9×10^{-1}
Human equivalent dose ug/kg/day	0	0	0.04	0.08	0.15	-------------
FEMALE (450g)[d]						
Number of animals examined	75	73	50	50	50	-------------
Hepatocellular carcinoma (HC)	0	0	0	0	2(4%)	3.2×10^{-1}
Neoplastic nodule (NN)	2(3%)	1(1%)	5(10%)	7(14%)[c]	16(32%)[e]	3.3
HC + NN combined	2(3%)	1(1%)	5(10%)	7(14%)[c]	18(36%)[e]	3.5
Human equivalent dose ug/kg/day	0	0	0.03	0.06	0.12	-------------

a. 95% upper-limit estimate of linear term in the multistage model based on human equivalent dosages using surface area correction.
b. Analysis by NCI (1980)
c. $p < 0.05$ versus vehicle-control
d. Reevaluation by Hildebrandt (1983)
e. $P < 0.001$

Table 3. HxCDD (Gavage) BIOASSAY (NCI, 1980):
B6C3F1 MICE (2 years)-INCIDENCES OF HEPATOCELLULAR CARCINOMAS AND HEPATOCELLULAR ADENOMAS

Tumor	Vehicle Control	Untreated Control	Low-Dose 1.25	Mid-Dose 2.5	High-Dose 5.0	Estimates[a] of q_1^* $(ug/kg/day)^{-1}$
(MALES)						
Number of animals examined	73	75	50	49	48	--------------
Hepatocellular carcinoma (HC)	8(11%)	12(16%)	9(18%)	5(10%)	9(19%)	3.71
Hepatocellular adenoma (HA)	7(10%)	15(20%)	5(10%)	9(18%)	15(31%)[b]	6.99
Combined HA and HC	15(21%)	27(36%)	14(29%)	14(29%)	24(50%)[c]	11.00
Human equivalent daily dose (ug/kg/day)	0	0	0.014	0.027	0.054	--------------
(FEMALE)						
Animal dose (ug/kg/wk)	0	0	2.5	5.0	10	--------------
Number of animals examined	73	74	48	47	47	--------------
Hepatocellular carcinoma (HC)	1(1%)	0	0	2(4%)	2(4%)	9.15×10^{-1}
Hepatocellular adenoma (HA)	2(3%)	2(3%)	4(8%)	4(9%)	9(19%)[b]	2.61
Combined HA and HC	3(4%)	2(3%)	4(8%)	6(13%)	10(23%)[b]	2.94
Human equivalent daily dose ug/kg/day	0	0	0.027	0.054	0.107	--------------

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a. 95% upper-limit estimate of linear term in the multistage model based on human equivalent dosages using surface area correction.

b. $p < 0.01$ versus vehicle-control

c. $P < 0.001$

Although the q_1^* for HxCDD could be as high as 11.0 $(ug/kg/day)^{-1}$, the Agency prefers to use the q_1^* of 6.2$(ug/kg/day)^{-1}$ for risk estimation for the reasons discussed above.

To estimate the potential risk(R)to humans from exposure to the HxCDD contaminant in pentachlorophenol and sodium pentachlorophenate, the Agency used the following equation:

$$R = 6.2 \times \text{exposure}$$

where the exposure is expressed in ug/kg/day averaged over a lifetime. The Agency assumes that the average worklife is 30 years.

The human exposure estimates for the various use situations for pentachlorophenol with its HxCDD contaminant are summarized in Appendix C of this document; the human risk estimates are summarized in Appendix B.

For similar exposure estimates, the potential estimates for HxCDD would be of the same order of magnitude as those presented in the PD 2/3. Although the tumor incidences for female rats are lower than originally reported, it only takes a very small amount of HxCDD (5 ug/kg/week or less) to produce a positive tumorigenic effect, and thus the slope or Q_1^*, as an indicator of potency would not be expected to decrease appreciably.

When comparing the risk estimates calculated in the PD 2/3 with those calculated for this PD 4, it can be seen that for some uses the risk has increased by an order of magnitude or more. This is due mainly to the changes made in the exposure assumptions discussed in section II B of this document.

3. Creosote

No new information was received by the Agency which changed the Agency's position regarding the rebuttable presumptions for creosote. As summarized in the PD 2/3 (pp. 36-46 and p. 85), creosote and many of its component chemicals have been shown to cause cancer in laboratory animals; there have also been many case reports linking human cancer to exposure to creosote. These findings have been updated and supported by a recent review of polynuclear aromatic hydrocarbons (IARC, 1983). However, as stated in the PD 2/3 (p. 85), the Agency still has no definitive data on the identity of the airborne component chemicals of creosote to which workers are exposed in wood treatment plants where creosote is used. Moreover, there are no quantitative data on dermal exposure to these workers. This lack of information precludes a quantitative assessment of risk of carcinogenicity in humans.

The Agency is aware that some researchers are studying the feasibility of interpolating results from skin painting studies which are validated against human carcinogens. However, creosote has not been tested or validated through this system.

Because the Agency continues to be concerned about the potential for high cancer risk from exposure to creosote, the Agency will, in a separate action apart from the requirements described in this PD 4, request registrants to submit a cross-sectional retrospective epidemiology study of creosote treatment plant workers to provide data with which to quantitatively estimate the oncogenic risk to humans. Study parameters such as sample size, identification of appropriate treatment plants, identification of comparison or control populations and other study parameters must be reviewed and accepted by the Agency prior to actual conduct of the study. Industrial hygiene air monitoring for exposure in creosote treatment plants will also be necessary and must include area and breathing zone data. Survey techniques should currently conform to standard methodologies approved by the Agency for regulatory purposes. The request will be made under the authority of FIFRA Section 3(c)(2)(B) to maintain in effect the existing registration of creosote products used as wood preservatives. The Agency believes the retrospective epidemiology study and creosote treatment plant monitoring survey will enable the Agency to quantitatively assess the potential human oncogenic risk from creosote exposure.

B. Exposure Information

The Agency received new information on exposure to the three wood preservatives which convinced the Agency to alter the assumptions made in the PD 2/3. The bases for the changes in exposure assumptions are presented in detail below. The changes are summarized in Tables 4 & 5 (Inorganic Arsenicals) and in Table 6 (Pentachlorophenol and its sodium salt). There is no table for creosote, as there was only one change.

1. INORGANIC ARSENICALS

a. AWPI (#36:30000/28C) stated that the air level of arsenic level to which workers may be exposed over an 8 hour period in wood treatment plants would not be as high the 0.07 mg/m^3 level estimated by the Agency in the PD 2/3. The 0.07 mg/m^3 estimate represented a time weighed average (TWA) found by the California Health Department (1979) in a survey of an arsenical treatment plant. The AWPI comment demonstrated that 0.07 mg/m^3 was based on the air level near a mixing area therefore overestimated the worker exposure. The Agency agrees and, in addition, the Agency has concluded that this plant was atypical because (1) its operations involved the mixing of powder formulations which are not widely used today, and (2) the formulations were mixed in an open area, not a closed system. AWPI stated that the level of 0.01 mg/m^3, would be more appropriate to use for purposes of estimating exposure. AWPI also submitted data (#36C:30000/28C) on urine level/airborne arsenic correlations which have convinced the Agency that 0.01 mg/m^3 is a more reasonable estimate (Day, Feb. 28, 1984).

Because of the above considerations the Agency has adopted the estimate of 10 ug/m^3 of arsenic in the ambient air for calculating exposure to applicators at arsenic treatment plants. The exposure estimates in Appendix B reflect this decision.

b. In the PD 2/3, the Agency assumed that respirators would provide 90% protection against inhalation exposure to the inorganic arsenicals. OSHA has found that "high efficiency filter" respirators provide 99% protection (29 CFR 1910.1018, Table 1). Because the Agency will require this type respirator if arsenic levels are either unknown or exceed 10 ug/m^3 in inorganic arsenical pressure treatment plants (see Section VI.C.1.), it will be assumed, as OSHA states, that the inhalation exposure is reduced by 99% instead of 90%. The inhalation exposure and exposure estimates with applicators using respirators, as presented throughout this PD 4, reflect the 99% reduction.

c. In the PD 2/3, the Agency assumed 100% inhalation absorption of arsenic from arsenic-laden sawdust, because no data were available to indicate otherwise. The Agency has revised the estimated inhalation absorption rates for sawdust containing inorganic arsenicals from 100% (PD 2/3) to 27% for chromated copper arsenate (CCA) and from 100% (PD 2/3) to 65% for ammoniacal copper arsenate (ACA) (Zendzian, Rebuttal Analysis, 1982; Zendzian, January 25, 1984; and Rispin, April 18, 1984). The revisions are based on an unpublished study by Peoples (1979) (AWPI Rebuttal #36:30000/28C) in which two beagle dogs were fed 2.0 grams of CCA-treated wood or 2.0 grams of ACA-treated sawdust for eight days. Neither dog showed signs of arsenic toxicity.

Table 4

Summary of Exposure Assumptions for the Inorganic Arsenicals for the PD 2/3 and PD 4*

Exposure Situations	PD 2/3 Assumption	PD 4 Assumption
a. Ambient arsenic air levels at treatment plants	0.07 mg/m^3	0.01 mg/m^3
b. Percent protection by high efficiency filter respirators	90%	99%
c. Inhalation absorption rates for CCA-and for ACA-laden sawdust; arsenic-laden dust	100% 100% 100%	27% 65% 100%
d. Dermal absorption rate for arsenic from arsenic-laden sawdust (CCA or ACA)	0.01%	Negligible
e. Dermal absorption rate for inorganic arsenic for: -liquid formulation -dry arsenic-laden dust	 0.1% 0.01%	 0.1% 0.1%
f. Dermal exposure to FCAP when emptying bags of FCAP powder	up to 10 grams	0.0038 to 0.142 mg/hr.
g. Inhalation absorb-tion for sawing arsenic treated wood	0.36 mg/m^3	0.024 mg/m^3
h. Arsenic air levels in homes constructed with arsenic treated wood	0.031 ug/m^3	0.004 ug/m^3

*See text for the bases of the exposure assumptions

The percentage of arsenic excreted in the urine and feces was measured. This study indicated that in the CCA-treated dog, 97.6 percent of the dose was excreted, with 27% of that amount excreted in the urine. The gastrointestinal absorption was thus calculated to be approximately 27% (i.e., 27% of 97.6%). In the ACA-treated dog, 80.7% of the dose was excreted, with 82% of that excreted in the urine. The gastrointestinal absorption was calculated to be approximately 65% (82.% of 80.7%).

Lacking other data, the Agency assumes that absorption of arsenic from arsenic-laden sawdust from inhalation exposure is the equivalent to absorption by the oral route (Rispin, April 18, 1984). The Agency assumes that 10% of the arsenic-laden sawdust will be respirable and that the remaining non-respirable dust will enter the gastrointestinal tract (PD 2/3, p. 213). The material would be deposited in the bronchial passageways, brought up by ciliary action and swallowed; absorption would then follow from the digestive tract (Zendzian, Rebuttal Analysis, 1982). Based upon the results of the study, the Agency has lowered the estimate of inhalation absorption rates for arsenic from sawdust containing arsenic, accordingly. Even though only two dogs were studied, the Agency determined that these data would be used to calculate an estimate for inhalation absorption rates for arsenic-laden sawdust in the absence of other existing data.

The Agency continues to assume, as in the PD 2/3 (pp. 203 and 210), that the inhalation and gastrointestinal absorption rate of arsenic-laden dust found in the ambient air at arsenic treatment plants or in homes constructed with All-Weather-Wood-Foundations is 100%, since the Agency lacks data that indicate otherwise (Rispin, April 18, 1984).

d. The Agency assumed in the PD 2/3 that the dermal absorption of arsenic from arsenic-laden sawdust was 0.01% (PD 2/3, pp. 199 and 209). A dermal absorption study by Peoples (unpublished, July 1979) submitted by AWPI (#36:30000/28C) has convinced the Agency that the dermal absorption of arsenic from arsenic-laden sawdust or dry arsenic-treated wood is negligible (Zendzian, Rebuttal Analysis, 1982; and Zendzian, April 16, 1982).

An area of skin on the back of each of two dogs was closely clipped. Urine from each dog was collected daily during the control (2 days) and treatment periods and was analyzed for arsenate (As V), arsenite (As III), methyl arsenate (MA) and dimethyl arsenate (DMA).

After the two-day control period, one dog had 1.5 gm fine southern pine sawdust from wood treated with CCA-C spread on a pad which was applied for two days in intimate contact to the skin with a plastic bandage. The sawdust contained 3.0% pentavalent arsenic.

After the-two day control period the second dog had 1.5 gm of ACA treated Douglas fir sawdust containing 6.7% arsenate applied in the same manner for three days.

No evidence of arsenic absorption was seen with either dog. Therefore, the Agency assumes there is negligible dermal absorption of arsenic from arsenic-laden sawdust or dry treated wood. The exposure estimates presented in this PD 4 reflect this change.

e. The Agency assumed (PD 2/3, p. 195) that the dermal absorption of inorganic arsenic in aqueous solution was 0.1% and that the dermal absorption from skin contact with dry arsenic-laden dust was 0.01%.

The Agency has revised the assumption for dermal absorption of inorganic arsenic from arsenic-laden dust from 0.01% to 0.1% based on a study by Datkizwicz (1977) which showed the upper limit for dermal absorption of arsenic from aqueous solutions of sodium arsenate was 0.1% (Zendzian, 1980). The dry arsenic-laden dust could become wet with perspiration and thus have a dermal absorption equivalent to that of arsenic in an aqueous solution. The exposure estimates summarized in Appendix C of this document reflect the assumption that dry arsenic-laden dust found in such settings as treatment plants or homes has a dermal absorption rate of 0.1% (Zendzian, April 14, 1982). The dermal absorption for inorganic arsenic in aqueous solution remains 0.1% (Rispin, April 18, 1984), as assumed in the PD 2/3 and is also based on studies by Datkizwicz (1970).

f. Regarding the emptying of bags of powder Fluor Chrome Arsenic Phenol (FCAP), the Agency estimated in the PD 1 and PD 2/3 that applicators would be dermally exposed to up to 10.0 grams of the dust concentrate. This estimate was not based on any actual exposure data. There are, however, exposure studies in which dermal exposure was measured during formulation and bagging operations with pesticide powders and dusts. (Comer et al., 1975; Jegier, 1964; and Wolfe et al., 1978). In the absence of data on FCAP, the Agency believes that the data from the cited studies can be used to estimate potential dermal exposure (Table 5). Assuming a maximum dermal absorption of 0.1% and 9.59% arsenic in FCAP, the Agency estimates the dermal exposure for FCAP during bag emptying to range from 0.0038 to 0.142 mg/hr. The Agency assumes bag emptying occurs one hour per day during an 8-hour work shift (Rispin, April 18, 1984). The Agency continues to assume, as in the PD 2/3, that the inhalation and gastrointestinal rate of absorption for water soluble salts of inorganic arsenic is 100%; the Agency has no data to indicate otherwise (Rispin, April 18, 1984).

g. The Agency had estimated the air concentration of arsenic while sawing, nailing or fabricating with arsenic treated wood to be 0.36 mg/m^3, (PD 2/3, p. 199). Data from a study at the University of Minnesota submitted by AWPI (#36C:30000/28C) convinced the Agency that a more reasonable estimate is 0.024 mg/m^3, the highest value in a Time-Weighted -Average (TWA). The exposure and risk estimates for sawing arsenic-treated wood in this PD 4 reflect this modification. However, the Agency continues to assume as in the PD 2/3 (p. 208) that 10% of the arsenic-laden sawdust particides will be respirable and that 90% is non-respirable but is deposited in the gastrointestinal tract (Rispin, April 18, 1984). As discussed above, 27% CCA-laden sawdust and 65% ACA-laden sawdust inhaled or swallowed will be absorbed by the body (Zendzian, Rebuttable Analysis, 1982).

h. The Agency had estimated (PD 2/3, p. 186) the air concentration of arsenic at 0.031 ug/m^3 in homes with All-Weather Wood Foundations. Data submitted by Koppers (Nov. 15, 1983) has convinced the Agency that a more realistic estimate for homes constructed with arsenic pressure-treated wood is an upper limit of 0.004 ug/m^3. The highest net increase over "blank" controls was 0.002 ug/m^3. The oncogenic risk estimation for people living in such homes reflects this change in exposure estimation, i.e. 0.004 ug/m^3 instead of 0.031 ug/m^3.

TABLE 5

Dermal Exposure (mg/hr)[a] During Pesticide Formulation

	Mean	Range	Dermal Estimate for Arsenic in FCAP
Mixing and bagging of 4-5% carbaryl dust[c]:	73.9	0.8-1209	142
Formulating 25% Guthion wettable powder[d]:	10.1	4.9-20.9	3.8
Formulating disulfoton as 0.5% dry mix fertilizer[e]:	2.0	0.1-10.5	38

a. Assumes workers were wearing short-sleeved shirts, no gloves or hats, and that covered areas of the body were protected from exposure.

b. Assumes worker is handling bags of (FCAP) containing 9.59% arsenic as metal.

c. From Comer *et al*. (1975).

d. From Jegier (1964).

e. From Wolfe *et al.*, (1978).

2. PENTACHLOROPHENOL

a. AWPI (Rebuttal #36:30000/28C) took issue with the Agency's estimate of the maximum amount of time workers spend opening and emptying bags of prilled or flaked pentachlorophenol and mixing pentachlorophenol solutions. AWPI stated that, with the Agency's PD 2/3 estimate, more pentachlorophenol would be mixed than is used annually. Based on the information provided in the rebuttal and evaluated by the Agency, the Agency has determined that a more accurate exposure estimate for workers who open and empty bags of prilled pentachlorophenol and mix prilled or flaked formulations of pentachlorophenol is 2 hours a day for two days a week instead of the PD 2/3 estimate of 4 hours a day for 5 days a week. The Agency has made the same assumption for mixing and emptying bags of powdered sodium pentachlorophenate.

b. Inhalation exposure data submitted by the USDA in response to the PD 2/3 confirmed that volatilization of pentachlorophenol from treated wood in an enclosed area is expected. The Agency had assumed (PD 2/3, p. 330) that for brush-on home and farm use the concentration of pentachlorophenol in the air in interior settings was 40 ug/m^3. However, the USDA (1981) supplied data which indicate that vaporization of pentachlorophenol from non-pressure treated wood should be revised to 34-140 ug/m^3 for vaporization in interiors for industrially dipped treated wood. Data also indicate that for older structures containing pentachlorophenol pressure-treated wood the pentachlorophenol concentrations in the air range from 0.5 to 10 ug/m^3 (Day, 1982). In addition, USDA (1981) provided the Agency with data which demonstrate that sealers can decrease by 85% the volatilization of vapors from pentachlorophenol-treated wood. The Agency has used the above measured levels to calculate risk from exposure to treated wood in interiors. Since available data do not suggest a significant difference between air levels from pressure-treated wood and those produced from brush-on applications of over-the-counter formulations (PD 2/3, p. 335), these estimates also will apply to potential exposure estimates in this document resulting from the use of pressure-treated lumber indoors.

c. Based on acute animal studies (Gaines, 1969), the Agency reassessed the dermal absorption rate for pentachlorophenol in organic solvents and has revised the assumption of 10% absorption (PD 2/3) to 50% absorption (Zendzian, 1981). The Agency has utilized the acute toxicity data of Gaines to determine an "apparent" dermal absorption rate. Gaines reported that in rats the oral LD_{50} of pentachlorophenol dissolved in peanut oil is 146 mg/kg in males and 175 mg/kg in females while the dermal LD_{50} of pentachlorophenol dissolved in xylene is 320 mg/kg in males and 330 mg/kg in females. From these data, the Agency calculated an "apparent" dermal absorption rate of 50%, because the dermal LD_{50} is approximately twice that of the oral LD_{50}. Exposure by the dermal route has been recalculated accordingly, using 50% instead of 10%, in this document for pentachlorophenol.

d. For sodium pentachlorophenate, in the PD 2/3 the Agency had assumed that the dermal absorption was the same as for pentachlorophenol, i.e., 10%. After reconsidering this estimate, the Agency has concluded that the dermal absorption of sodium pentachlorophenate would be no more than 1.0%, because it is in an aqueous solution, not an organic solvent as is pentachlorophenol (Day, Dec. 9, 1983). A sodium salt of pentachlorophenol in an aqueous solution is expected to have less dermal absorption than pentachlorophenol in an organic solvent. The risk estimates for uses of sodium pentachlorophenate in this document reflect this revised exposure (1.0% instead of 10%).

e. For HxCDD, the Agency assumed in the PD 2/3 that the dermal absorption rate was same as for pentachlorophenol, i.e., 10%. New data (Poiger and Schlatter, 1980) on another dioxin, tetrachlorodibenzo-p-dioxin (TCDD), indicate that the dermal absorption rate in rats for TCDD is approximately 50%. Because the chemical structure of HxCDD is more similar to that of TCDD than to pentachlorophenol, the Agency assumes the dermal absorption rates for HxCDD and TCDD are more likely to be similar. Therefore, the Agency assumes the estimated rate of dermal absorption for HxCDD is 50% instead of 10% (Rispin, April 24, 1984).

f. In the PD 2/3, the Agency assumed that gloves afforded 99% protection from dermal exposure to the hands when applying pentachlorophenol formulations. New data by Silkowski (1982) on penetration of pentachlorophenol through various materials [rubber, polyvinyl chloride (PVC), neoprene, and nitrile rubber] has convinced the Agency that PVC, neoprene, and nitrile rubber will provide the best protection for the applicator of pentachlorophenol products. Based on these data and normal use patterns for workers wearing gloves, the Agency estimates that gloves made from PVC, neoprene, or nitrile rubber can be relied upon to provide 90% protection to the applicator (Rispin, April 24, 1984). This estimate takes into account the possibility of some of the pesticide formulation seeping around the cuff of the glove or contacting the treatment solutions on the gloves themselves when the gloves are taken off.

g. A study presented at the International Symposium on Indoor Air Pollution, Health and Energy Conservation (1981) and a rebuttal submitted by AWPI (#36:30000/28C) provided information on the time a resident would spend in a home. Instead of using the PD 2/3 estimate of 24 hours as the time spent at home, the Agency has evaluated the additional information and has revised this to the more representative estimate of 15 hours (8 hours resting, 1 hour heavy work, and 6 hours light work) (Day, Exposure Analysis, 1982). This exposure estimate was used in the determinations of risk in this document from inhalation exposure to treated wood in interiors. The Agency is aware that various sub-groups of the population of the United States may spend as much as 24 hours in the home, such as some housewives and young children in the winter, the elderly at home, and people in nursing homes, hospitals, nurseries. Section VIII of this document outlines the Agency's regulatory measures which will reduce exposures form pentachlorophenol vaporization from treated wood in interior settings.

The risk estimates which result from the changes in exposure assumptions for pentachlorophenol and the inorganic arsenicals are presented in this document in the sections discussing the specific uses of these wood preservatives. The risks from exposure to pentachlorophenol and the inorganic arsenicals are summarized in Appendix B.

Table 6

Summary of Exposure Assumptions for Pentachlorophenol, Sodium Pentachlorophenate and HxCDD for the PD 2/3 and PD 4*

Exposure Situation	PD 2/3 Assumption	PD 4 Assumption
a. Emptying bags of prilled or flaked pentachlorophenol, or powdered sodium pentachlorophenate	4 hrs/day 5 days/week	2 hrs/day 2 days/week
b. Inhalation exposure for pentachlorophenol in interiors from pentachlorophenol treated wood:	40 ug/m^3	34-140 ug/m^3
non-pressure	40 ug/m^3	34-140 ug/m^3
pressure	40 ug/m^3	0.5-10 ug/m^3
c. Dermal absorption rate for pentachlorophenol formulations	10%	50%
d. Dermal absorption for sodium pentachlorphenate formulations	10%	1.0%
e. Dermal absorption rate for HxCDD	10%	50%
f. Protection from pentachlorophenol afforded by gloves	99%	90%
g. Hours spent at home	24 hours	15 hours (8 hours rest, 1 hour heavy work, 6 hours light work).

*See text for the bases of the exposure assumptions.

3. CREOSOTE

The Agency has assumed (PD 2/3) that the concentration of creosote particles in the plant environment ranged from 45 to 95 ug/m^3. AWPI (#36A:30000/28C) submitted data which showed the concentration ranged from 20 to 9,000 ug/m^3. The Agency has reviewed these data and accepts the higher estimate for creosote particulates in the air in the plant environment (Day, December 9, 1983). However, as explained previously in Section II.A.3, no risk estimates have been calculated for creosote exposure due to a lack of data on (1) the identity of the airborne chemicals and (2) dermal exposure for workers using creosote. Because the Agency is concerned about the risk of cancer in applicators and the lack of data for quantification of risk, the Agency will require registrants to perform an epidemiology study including adequate air monitoring and dermal exposure data for risk estimation as described previously in Section II.A.3.

C. Benefit Information

The application of wood preservative chemicals protects wood from attack by fungi, insects, bacteria, or marine borers. In most situations, treating wood increases its life expectancy to five or more times that of untreated wood.

Pressure-treated wood is primarily used for: railroad ties; lumber, timber and plywood; pilings; posts; crossarms; and poles. Non-pressure treatment methods are used for poles groundline; home and farm; sapstain control; millwork and plywood; and particleboard.

For many uses, creosote, pentachlorophenol, and the inorganic arsenicals are potential substitutes for each other. Other alternative chemicals vary in cost and efficacy. Alternative materials such as steel, concrete, or untreated wood also vary in cost and practicality.

The Agency has estimated the economic impact of cancelling each use by calculating the cost of substituting other registered wood preservatives or alternative materials. The PD 2/3 contains a complete discussion of the impact estimation methodology. No new information has been received since the PD 2/3 which significantly changes the estimates made at that time. A brief summary of the projected economic impact for each use pattern is provided below.

Tables 7 to 9 briefly summarize and characterize the extent of the economic impacts of various cancellation scenarios.

1. Uses of Pressure-Treated Wood

a) Railroad ties.

Railroad cross and switch ties used in the United States are treated with wood preservatives. Approximately 99.6% of these ties were treated with creosote and the remaining 0.4% with pentachlorophenol. The predominant use of creosote-treated ties reflects their greater suitability in terms of performance and cost. Inorganic arsenical treatment is considered unacceptable for railroad tie use because inorganic arsenic-treated ties are brittle and do not hold fasteners well.

Concrete ties are technically feasible substitutes for treated wood ties; however, treated wood ties and concrete ties cannot be used in the same section of a railway tie system. Thus, replacing wood ties with concrete necessitates the replacement of all the ties in a given section of track.

The impact of cancelling creosote products registered for this use was analyzed in terms of the "annualized" or average annual cost, which represents the average yearly investment which is required to maintain the railroad system for a finite time period (the time period selected for this analysis was 100 years). The Agency considered three regulatory alternatives: (1) cancellation of creosote only; (2) cancellation of pentachlorophenol only; and (3) cancellation of both creosote and pentachlorophenol.

The Agency has determined that there would be an annualized long term cost increase of $40.5 million if creosote were cancelled and pentachlorophenol were still available for railroad tie use. During the first year, there would be a decline in cost of $18.2 million, due to the lower installation costs for pentachlorophenol-treated ties compared to creosote-treated ties.

Since less than 1% of railroad ties in the United States are treated with pentachlorophenol, there would be little or no adverse economic impact if pentachlorophenol were cancelled and creosote were still available to the railroad industry.

If both creosote and pentachlorophenol were cancelled, the most likely substitutes would be copper naphthenate-treated ties and concrete railroad ties. Either of these alternatives would substantially increase the cost of the nation's railroad tie system. The annualized cost of the system would increase by $0.58 billion during the first year and $0.74 billion thereafter if copper naphthenate-treated ties were used. It would increase by $3.7 billion during the first year and by $2.4 billion annually thereafter if concrete ties were used.

b. Lumber, timber and plywood. Declining supplies and higher prices for naturally resistant woods such as cedar and redwood have resulted in an increased demand for treated wood. Based on efficacy and other performance characteristics, wood treated with the inorganic arsenicals is suitable for most end-uses of lumber, timber and plywood. Inorganic arsenical-treated wood is clean, odorless, paintable, easy to handle, harmless to plants and more durable than other treated wood. Its uses include patios, decks, playground equipment, cooling towers, greenhouses, horticultural nurseries and all-weather wood foundations. In contrast, pentachlorophenol and creosote treated lumber, timber and plywood have limited uses due to odor, objectionable vapors, and oily, unpaintable surfaces. Despite its disadvantages, creosote is the only wood preservative which is satisfactory for use in interior industrial block flooring to protect the wood from mechanical wear.

Table 7

Summary of Economic Impacts of Cancelling Creosote*

Use	Cancel Creosote only	Cancel Creosote & Pentachlorophenol	Cancel Creosote & Arsenicals	Cancel all Three
Pressure:				
Railroad Ties	Minor	Major	Minor	Major
Lumber, Timber and Plywood	Minor	Moderate	Major	Major
Piling	Major	Major	Major	Major
Posts	Moderate	Minor	Major	Major
Crossarms	Minor	Minor	Minor	Major
Poles	Major	Major	Major	Major
Non Pressure:				
Poles-groundline	Minor	Major	Minor	Major
Home and Farm	Minor	Minor	Minor	Minor

* Impact descriptors were determined taking into account the following factors: 1) dollar impact and 2)total market, 3) disruption due to change to alternatives (e.g. capital investment), 4) aesthetic considerations, 5) cost and availability of alternatives and, 6) other use specific factors. For a more complete discussion of the economic impacts, see the PD 2/3 and material referenced there.

Table 8

Summary of Economic Impacts of Cancelling Pentachlorophenol (Penta)*

Use	Cancel Penta only	Cancel Penta and Creosote	Cancel Penta and Arsenicals	Cancel all Three
Pressure:				
Railroad Ties	Minor	Major	Major	Major
Lumber, Timber and Plywood	Major	Moderate	Major	Major
Piling	Major	Major	Major	Major
Posts	Moderate	Minor	Moderate	Major
Crossarms	Minor	Minor	Moderate	Major
Poles	Major	Major	Major	Major
Non Pressure:				
Poles-groundline	Minor	Major	Minor	Major
Home and Farm	Minor	Minor	Minor	Minor
Sapstain**	Moderate	Moderate	Moderate	Moderate
Millwork and*** Plywood	Minor	Minor	Minor	Minor
Particleboard	Minor	Minor	Minor	Minor

* Impact descriptors were determined taking into account the following factors: 1) dollar impact and 2)total market, 3) disruption due to change to alternatives (e.g. capital investment), 4) aesthetic considerations, 5) cost and availability of alternatives and, 6) other use specific factors. For a more complete discussion of the economic impacts, see the PD 2/3 and material referenced there.

** Sodium pentachlorophenate

*** While the economic impacts of a cancellation are considered to be minor in terms of absolute dollars, the impact would be significant for users who would not have any equally efficacious alternative chemical to apply.

Table 9

Summary of Economic Impacts of Cancelling the Inorganic Arsenicals*

Use	Cancel Arsenicals only	Cancel Penta** and Arsenicals	Cancel Arsenicals** and Creosote	Cancel all Three
Pressure:				
Lumber, Timber and Plywood	Major	Major	Major	Major
Piling	Minor	Major	Major	Major
Posts	Moderate	Moderate	Major	Major
Crossarms	Minor	Moderate	Minor	Major
Poles	Major	Major	Major	Major

* Impact descriptors were determined taking into account the following factors: 1) dollar impact, 2)total market, 3) disruption due to change to alternatives (e.g. capital investment), 4) aesthetic considerations, 5) cost and availability of alternatives and, 6) other use specific factors. For a more complete discussion of the economic impacts, see the PD 2/3 and material referenced there.

** Pentachlorophenol.

In 1978, more than 70% of the total treated lumber and timber, about 73.32 million cubic feet, was treated with inorganic arsenicals and about 20%, or about 21.21 million cubic feet of lumber and timber, was treated with pentachlorophenol.

Because of the wide variety of uses for treated lumber, timber and plywood, the Agency has not been able to quantify the anticipated economic impact if all three wood preservatives were cancelled for these uses. The Agency expects that non-wood materials such as plastic, steel or concrete would be substituted for the treated wood, and that these materials would have a higher cost than the wood.

The Agency believes that there would also be a major adverse economic impact if the inorganic arsenicals were cancelled, because pentachlorophenol and creosote-treated lumber, timber and plywood are not generally acceptable alternatives to the inorganic arsenical-treated lumber, timber and plywood.

If creosote were cancelled but the other two preservatives remained available, the Agency anticipates a first year cost increase in chemical costs and additional capital investiment of $39 million. The Agency anticipates an increase in cost of $18 million if only pentachlorophenol were cancelled. If both were cancelled, the estimated initial economic impact would be an increased cost of $5.2 million (a decrease in chemical cost coupled with increased capital costs). The costs of disruption in a major treated wood market would not be easily quantified.

c. Pilings. All three wood preservatives are currently being used to treat pilings. In 1978, creosote was used to treat 82.7% of pilings, pentachlorophenol for 9.5% and inorganic arsenicals for 7.8%.

Creosote is the preservative commonly used for building foundations and marine uses. Arsenic may be an acceptable substitute for creosote for both uses. However, treatment of wood with inorganic arsenicals makes it more brittle, increasing the likelihood of breakage of pilings both during mechanical driving and shipping. Pentachlorophenol may be used as an alternative to creosote for treating pilings for foundations but is not recommended or used for marine pilings. Both concrete and steel provide technically acceptable alternative materials for pilings in foundation uses. However, steel would be subject to corrosion in highly acidic soils or in marine environments.

The Agency believes that there would be an adverse economic impact if pentachlorophenol or creosote were cancelled for use on pilings. It anticipates a $9-10 million first year increase if creosote were cancelled and a $8.3-9 million first year increase if pentachlorophenol were cancelled. Since creosote would be an acceptable substitute for the inorganic arsenicals, the anticipated economic impact of cancelling the inorganic arsenicals would be minor.

If all three wood preservatives were cancelled, the most likely substitutes would be concrete for marine uses and steel for foundation uses. The costs for steel and concrete pilings (including installation costs) are higher than for treated wood pilings. Assuming a one to one replacement for the wood pilings, the total average annualized installed cost of pilings would increase 33.3% ($64.5 million) for concrete and 67% ($129.1 million) for steel compared to the 1978 cost of treated wood pilings.

However, if concrete and steel piles are assigned heavier loads than previously assigned to the treated wood piles, the total installed cost of pilings could decrease by as much as 11% for concrete and increase by as much as 11% for steel, compared to the 1978 annualized cost of treated wood pilings. The likelihood of assigning higher levels to concrete and steel pilings is entirely dependent upon the specific characteristics of the site and the building under construction.

d. Posts. Creosote, pentachlorophenol and the inorganic arsenicals are all used to treat fence posts. In 1978, 22.9% of the posts were treated with creosote, 54.8% with pentachlorophenol and 22.3% with the inorganic arsenicals. The estimated plant value of treated wood posts in 1978 was $66.1 million (USDA, #1980, p. 321).

If pentachlorophenol were cancelled, there would be an annual increase of $0.75 million to $5.1 million in the cost of treated wood posts, depending on whether creosote or inorganic arsenicals are used as an alternative. If creosote were cancelled, there would be a $3.3 million annual cost increase for the first and subsequent years. If the inorganic arsenicals were cancelled, the first year and annual long-term impacts would be a cost increase of $4.0 million to 4.5 million in treated wood posts depending on which alternative (e.g., creosote or pentachlorophenol) is chosen.

If both creosote and the inorganic arsenicals were cancelled, the annual cost increase is estimated to be greater than $7 million for treated wood fence posts. If both the inorganic arsenicals and pentachlorophenol were cancelled, there would be an annual increase in post cost of greater than $5.1 million. Under this cancellation scenario, steel posts would probably replace treated wood posts for suburban uses since creosote-treated posts are unacceptable replacements. If both creosote and pentachlorophenol were cancelled, this impact is estimated, based on current levels of usage, to be an annual cost increase of $383,000.

If all three wood preservatives were cancelled, steel or concrete posts would be the most likely alternative materials that could be used for fence posts. T-type steel posts, which serve as substitutes for treated wood posts in farm uses, are priced competitively with treated wood posts. Thus, substitution of steel posts in many farm uses would not necessarily lead to much higher fencing cost. An increase in demand, however, could lead to increased costs of steel posts. Farmers' preference for treated wood posts would indicate that treated wood posts are superior to the metal posts from the standpoint of cost or performance (USDA, 1980, p. 325). Concrete posts would be more expensive than steel and would not be substituted in most farm situations.

e. Crossarms. Crossarms are the cross members of assembled utility poles. The distribution of crossarms by preservative treatments was 2.5% for creosote, 95.8% for pentachlorophenol and 1.7% for the inorganic arsenicals. The 1978 cost of treated crossarms was estimated as $14.86 million. Steel crossarms are used as alternatives for treated wood crossarms by some utility companies (USDA, 1980, p. 313).

If pentachlorophenol were cancelled for the crossarm use, there would be economic impacts for both the first and subsequent years ranging from a decline in annual cost of $0.23 million to an additional annual cost of $1.2 million, depending upon which alternative (creosote or inorganic arsenicals) is chosen. If creosote were cancelled, there would be first year and annual long-term impacts, ranging from a decline in cost of $15,000 to $30,000, also depending on which alternative (e.g., inorganic arsenicals or pentachlorophenol) is chosen. These economic impacts are based on current preservative prices and do not include any additional investment costs for conversion from one treatment process to another. If the inorganic arsenicals were cancelled, there would be a slight increase in treated crossarm cost.

If both the inorganic arsenicals and pentachlorophenol were cancelled, there would be an additional annual cost of $1.2 million for treated crossarms. If both the inorganic arsenicals and creosote were cancelled for the crossarm use, there would be an annual decline in costs of $0.2 million. If pentachlorophenol and creosote were cancelled, there would be a small decline in the annual cost of treated crossarms.

If all three wood preservatives were cancelled, the most likely substitute would be steel crossarms. Steel crossarms would perform competitively with treated crossarms (USDA, 1980). This cancellation scenario would, however, most likely result in higher crossarm costs.

f. Poles. The distribution of the three preservatives for pole treatment by volume in 1978 was 65.3% for pentachlorophenol, 38.4% for creosote and 6.3% for the inorganic arsenicals. There are no viable chemical alternatives for the three major wood preservative agents for pole treatment with the possible exception of copper naphthenate for certain limited uses. Non-wood alternatives for treated poles include the use of concrete and steel as pole construction materials and the installation of underground distribution and transmission lines in urban areas or in new subdivisions.

If pentachlorophenol were cancelled for poles, there would be a first year cost increase, ranging from $19.9 million to $24.2 million depending upon which alternative is chosen (e.g., creosote or the inorganic arsenicals). The long-term economic impact for the cancellation of pentachlorophenol would range from a total annualized cost decrease of $43.6 million to an annualized increase of $32.8 million. If creosote were cancelled, there would be a first year additional cost of $9.4 million to $20.7 million. The additional costs include the impact of a preservative price increase and the capital expenditures required for plant modifications (USDA, 1980, p. 306). The long-term impact would range from an average annual decline in cost of $43.6 million to an additional cost of $17.8 million depending on the alternative chosen. If the inorganic arsenicals were cancelled, there would be an additional cost of $1.9 million for the first year and an additional cost of $17.8 million to $32.8 million for each subsequent year.

If pentachlorophenol and creosote were cancelled, there would be an additional first year cost of $28 million and an annual decline in cost of $43.6 million in subsequent years. This is due to the estimated service life of arsenic-treated poles being much longer than creosote or penta chlorophenol treated poles, thus reducing the average annual cost. If pentachlorophenol and the inorganic arsenicals were cancelled, there would be a cost increase of $34.5 million in the first year and an average annual cost increase of $32.5 million in the subsequent years. The cancellation of creosote and the inorganic arsenicals would result in an additional first year cost of $24.3 million and an average annual cost increase of $18 million in subsequent years. If all three major wood preservatives were cancelled for poles, the most likely substitutes would be concrete and steel. Under this cancellation scenario, there would be large cost increases ranging from $1.3 billion to $2.1 billion annually depending upon the alternative chosen.

2. Non-pressure uses of treated-wood

a. Poles-groundline. Although the treatment of inplace utility poles at groundline (poles-groundline) represents a small segment of the wood treatment industry, it is an important wood preservative use. Wood preservatives are applied to a previously installed pressure-treated pole over a section covering the six inches above and sixteen inches below the ground level of the pole. This treatment can delay decay and subsequent pole failure for 20 years or more. Approximately 1 million poles received groundline treatment in 1978.

The two major formulations of commercial poles-groundline treatments marketed in the United States contain both creosote and pentachlorophenol. One of these formulations has a high creosote content and the other a high pentachlorophenol content (the latter product also contains sodium fluoride). Currently, the high creosote formulation is used for about two-thirds of all poles-groundline treatments and high pentachlorophenol content product is used for about one-third.

If either pentachlorophenol or creosote were cancelled, the economic impact would be minor, because the remaining registered wood preservative would be substituted for the cancelled one. However, if both pentachlorophenol and creosote were both cancelled for the poles-groundline use, the anticipated longterm economic impact would be major. There would be an average annual cost ("annualized") increase of about $36.8 million. Moreover, if the current level of groundline treatment doubles in the next five years (USDA, 1980, p. 378), the increase in annualized pole replacement costs would exceed $70 million. There would be an initial savings of $10.2 million per year (the estimated cost for the treatment of 1 million poles) if the poles were not being treated with either pentachlorophenol or creosote (USDA, 1980 p. 378).

b. Home and farm. Homeowners, farmers, and on-the-job carpenters apply pentachlorophenol and creosote for home and farm uses, by a variety of techniques, including brushing, rolling, dipping, soaking and spraying. The inorganic arsenical preservatives are not generally available to home and farm applicators because of current marketing practices.

About 1.6 million pounds of pentachlorophenol and 2.0 million pounds of creosote are used around homes and farms to protect various wood structures and products exposed to natural elements. They extend the useful service life of wood in above-ground applications and provide limited protection for wood in contact with the ground. Typical treated wood items include decks, siding, millwork, lumber, fences, shingles and outdoor furniture.

Homeowners and farmers would have alternative means of protecting structures and products exposed to the elements if pentachlorophenol or creosote were cancelled.

Copper naphthenate, copper-8-quinolinolate, zinc naphthenate and tributyltin oxide (TBTO) are currently available to homeowners and farmers, but cost somewhat more than either pentachloropheol or creosote. Moreover, these chemicals do not have the wide range of control characterisitics of the latter.

Pressure treated lumber may be purchased at a cost somewhat higher than lumber treated by brush or dip application. However, it is not a suitable alternative for all non-pressure home and farm uses. (Where it can be appropriately used, pressure-treatment provides better protection to wood than non-pressure applications.)

Non-wood materials such as aluminum and concrete can replace treated wood in some circumstances at comparable prices. However, the comparability of cost does not take into account the aesthetic value of wood.

c. Sapstain control. Although the most serious structural damage to wood is caused by insects and decay, infestation with sapstain fungi increases the capacity of the wood to absorb moisture, thus making the wood more vulnerable to decay. Sapstain fungi infestation also causes discoloration which reduces the market value of the wood. Currently, sodium pentachlorophenate (sodium penta) is the primary antimicrobial used to control sapstaining and surface staining fungi in the United States. About 1.15 million pounds of sodium penta are used annually for this purpose. These sodium penta solutions often include the salts of other chlorinated phenols.

The alkali salts of tetrachlorophenol (tetra) have been used effectively for sapstain control for over 40 years; in recent years, however, sodium penta has replaced sodium tetra as the primary antimicrobial for sapstain control. Copper-8-quinolinolate (Cu-8) is also currently registered for sapstain control; however, information is unavailable on the volume of Cu-8 used for sapstain control and the effectiveness of this chemical for this use. Kiln drying can be used to prevent sapstain for most softwoods; however kiln drying cannot be utilized in those situations where freshly-cut lumber cannot be placed in the kiln within 48 hours. Kiln drying is also not appropriate for a number of hardwood species which are subject to warping and honeycombing during kiln drying.

The Agency has determined that there would be a minor adverse economic impact if sodium penta were cancelled. The most likely substitutes for controlling sapstain would be the alkali salts of tetrachlorophenol (e.g., sodium tetra or potassium tetra), which are equal in cost and efficacy to sodium penta. Other alternatives (e.g., Cu-8) are available at a slightly increased cost; these alternatives, however, may not provide adequate protection for sapstain control.

d. Millwork and plywood. Millwork and plywood are usually treated with a 5% pentachlorophenol solution in mineral spirits (containing water repellants) which is applied by spraying, brushing, dipping or by the vacuum process. Available chemical alternatives for millwork include TBTO and copper-8-quinolinolate (Cu-8) but some formulations may not be as efficacious as pentachlaorophenol (PD 2/3, p. 526). A water-based Cu-8 formulation has not yet been shown to be effective. A 0.75% TBTO has shown effectiveness for above ground exposure when the millwork is painted (PD 2/3, p. 527). The available chemical alternative for plywood is TBTO for those uses where the treated plywood could be painted. The effectiveness of Cu-8 for plywood has not been proven by actual field use experience (PD 2/3, p. 528).

The Agency has determined that there would be a minor adverse economic impact to the millwork and plywood industry if pentachlorophenol were cancelled. Millwork and plywood manufacturers could choose to use 0.75% TBTO, which costs about the same as pentachlorophenol, and is effective for above ground exposure if the TBTO treated wood is painted.

The water-based Cu-8 solution, may prove to be efficacious. If so, many pentachlorophenol users could use this formulation. Other alternative materials that could be substituted for pentachlorophenol are untreated wood, which would require frequent replacements and increase the demand for wood products, naturally resistant wood, and non-wood materials (e.g., aluminum). Due to the short supply of naturally resistant wood and the frequent replacements required for untreated wood, the most likely non-chemical alternative would be the use of non-wood materials. Naturally resistant wood (e.g., red cedar and redwood) can cost 2 to 3 times as much as treated southern pine (USDA, 1980, p. 340-345). Non-wood materials (e.g., concrete, metal, aluminum, plastic, etc.) can cost more than or less than treated wood depending on the material and the end use. Aesthetics and the purpose or function of a structure are important determinants in selection of materials. It is difficult to estimate the value associated with these determinants.

e. Particleboard. In some areas of the United States, it may be necessary to use treated particleboard to prevent attack by dry-wood termites and other wood destroying insects. Pentachlorophenol is presently the only preservative used for this specific purpose. There is currently only one known plant producing pentachlorophenol-treated particleboard. The treated particleboard constitutes less than 1% of the average annual particleboard production at the plant and represented a very small part (about 0.005%) of the 3.9 billion square feet of particleboard produced in the United States in 1978 (USDA, 1980 p. 385).

The production of treated particleboard generates an annual revenue of about $35,000. Thus, even though there are no registered alternatives for the particleboard use, the economic impacts to the user would be minor if pentachlorophenol were cancelled for this use. Untreated particleboard would be used in place of treated board. Although less expensive, the untreated particleboard would be more susceptible to potential infestation of termites and other wood-destroying insects.

III. SCIENTIFIC ADVISORY PANEL (SAP) COMMENTS AND AGENCY RESPONSE

The Scientific Advisory Panel (SAP) held an open meeting on June 17-19, 1981, in Arlington, Virginia, to review the Preliminary Notice of Determination concluding the RPAR for the wood preservative chemicals. At this meeting, the SAP heard presentations by the Agency, the registrants, and other interested members of the public. The Agency requested the SAP to review several issues relating to the wood preservatives. The SAP submitted its comments on the Preliminary Notice of Determination and its recommendations on July 15, 1981. This submission is included in its entirety in this document as Appendix D. A summary of the SAP comments and the Agency's response to those comments is as follows:

A. Pentachlorophenol

Issue #1

The Agency stated in the PD 2/3 that a no-observed-effect level (NOEL) for teratology could not be accurately determined and asked the SAP if the occurrence of delayed skull ossification at 5.0 mg/kg/day would preclude the establishment of a NOEL at that level. The SAP commented that the establishment of a NOEL is precluded both by the litter loss phenomenon and by the delayed skull ossification at 5.0 mg/kg/day.

Agency Response

Although the Agency agrees with the SAP that an accurate teratogenicity/fetotoxicity NOEL for pentachlorophenol cannot be determined, in order to estimate the margins of safety for teratogenic/fetotoxic effects, the Agency has chosen a provisional NOEL of 3 mg/kg/day based on a one-generation reproduction study by Schwetz et al. (1978). Schwetz reported a trend toward decreased neonatal weight at a dose of 3 mg/kg/day (Van Ormer, May 21, 1982). The margins of safety (MOS) for pentachlorophenol, cited throughout this Position Document and summarized in Appendix B, were calculated on the basis of the provisional NOEL of 3 mg/kg/day.

Issue #2

The Agency asked the SAP for their opinion whether human health would be adequately protected if over-the-counter sales of 5% or less pentachlorophenol were allowed to continue. The SAP stated that human health would be adequately protected if the label required that protective clothing, including rubberized gauntlets, goggles, and coveralls be worn, and that all applications take place in a well-ventilated area.

Agency Response

Because of the changes in risk and exposure estimates discussed in Section II of this document, the risks to homeowners and farmers applying pentachlorophenol formulations containing less than 5% pentachlorophenol have increased. The potential oncogenic risks for applicators using gloves have increased by a factor of approximately 5 from 1.3×10^{-6} (PD 2/3, p. 656) to 6.2×10^{-6}.

However, the margin of safety for fetotoxic effects has decreased from 560 (PD 2/3, p. 660) to 12. Thus, women who are pregnant and who use a 5% pentachlorophenol wood preservative product have a potential margin of safety (MOS) of 12 for giving birth to a child with evidence of some degree of fetotoxicity. The assumptions made for risk estimation were that a woman wearing gloves with 90% protection accidentally spills 6.0 mls to cover both hands during one application of a 5% pentachlorophenol solution.

The Agency has concluded that for this use situation, the benefits of use of "over-the-counter" pentachlorophenol products by home and farm applicators do not outweigh the risks. Therefore, the Agency requires that use of these products will be for certified applicators only, that there be a warning on the labels concerning potential hazard for fetotoxic effects as discussed in Section II of this document, and that impermeable gloves and protective clothing be worn by the certified applicators as discussed in Section VI.E of this document.

Regarding the SAP recommendation for wearing gauntlets, the Agency has learned from field observations by Agency personnel that workers found gauntlets cumbersome and too hot to wear, and often cut them to "glove" length. The Agency has concluded that gloves impermeable to the pesticide will adequately protect the worker from hand dermal exposure and that coveralls will adequately protect the applicator from dermal exposure to parts of the body other than the hands.

Regarding the SAP recommendation that applicators wear goggles, the Agency agrees that goggles are necessary for certified applicators, to prevent the pentachlorophenol formulations from getting into their eyes during application.

Application of pentachlorophenol in residential interiors, will be prohibited, but outdoor application will be allowed. This satisfies the SAP recommendation that application of pentachlorophenol take place in a well-ventilated area.

Issue #3

The PD 2/3 proposed prohibiting the use of pentachlorophenol on the interior surfaces of living quarters. At the meeting with the SAP, the Agency asked the Panel for opinions regarding the need for further exposure studies of log homes constructed with pentachlorophenol-treated wood. The SAP recommended a more critical review of the fate of pentachlorophenol in the environment, an assessment of human urinary excretion of pentachlorophenol, and the development of additional exposure and epidemiological studies.

Agency Response

The Agency has determined, as discussed in Section VI.H.3., that application of pentachlorophenol to logs which are intended for use in the construction of log homes must be prohibited.

The Agency has further determined, based on information discussed in Section VII.A.4 of this PD 4, that pentachlorophenol pressure-treated wood should not be used in residential interiors, except for laminated beams and building components which are in ground contact and are subject to decay or insect infestation, and then only if two coats of an appropriate sealer are applied.

The rationale for this decision is based in part on information on effects in people exposed to pentachlorophenol in interiors provided in response to the PD 2/3 and the public meeting held April 14, 1983, by Levin (#60:30000/28C), Friends of the Earth (#70:30000/28C), and the Center for Disease Control (#71:30000/28C) as well as reports entered into the U.S. EPA Pesticide Incident Monitoring System (PIMS, 1981).

As discussed in Section II of this PD 4, USDA (1981) submitted exposure data on the vaporization of pentachlorophenol from non-pressure dip-treated wood with and without sealers. The data showed that sealers reduce pentachlorophenol vaporization by approximately 85%, but there were no data to indicate the length of time of effectiveness of the sealers. A reapplication of sealer may be necessary at a latter date for continued vapor reduction.

Information was also submitted to the Agency on pentachlorophenol levels in the urine of occupants of a new state office building constructed with pentachlorophenol pressure-treated beams in Long Beach, California (#86:30000/28C, Jackson and Stratton, Oct. 19, 1983). None of 37 volunteers had a detectable level of free pentachlorophenol in their urine prior to occupancy, but more than half did after the first two weeks of occupancy. After the pentachlorophenol was sealed, there were measurable levels averaging 5 ug/m^3 pentachlorophenol in the air inside the building. Prior to sealing the wood, air levels were 50 ug/m^3, a level previously shown to be associated with acute toxic effects (#86:30000/28C).

AWPI (#36B:30000/28C, p. 44) commented that in highly enclosed spaces, pentachlorophenol should not be used to preserve a large portion of interior wall space.

Regarding log homes, Amburgey and Williams of Mississippi State University (Dec. 1982) stated that chemical alternatives are available as wood treatments.

Based on the above information, applying pentachlorophenol (non-pressure treatment) to logs to be used in the construction of log homes will be prohibited and the Consumer Information Sheet (Section VII. C) will state that pentachlorophenol-treated wood (pressure-treated) should not be used in interiors except for limited uses and then only if properly sealed.

As discussed in Section V of this document, epidemiological studies of workers exposed to pentachlorophenol (AWPI#81:30000/28C) were submitted and evaluated by the Agency, but the results were inconclusive. The Agency is satisfied that the changes to the terms and conditions of registration outlined in Section VI of this document will assure adequate protection to man and the environment from exposure to pentachlorophenol when taking the benefits of use into account, and that further studies on pentachlorophenol are not necessary for regulatory decision-making.

Regarding the fate of pentachlorophenol in the environment, see Issue #5 and the Agency Response below.

Issue #4

The Agency asked if EPA should investigate the subject of the photolytic conversion of pentachlorophenol to hexachlorodibenzo-p-dioxin (HxCDD) and hexachlorobenzene. The Panel recommended that this area be investigated.

Agency Response

The Agency has concluded that the required regulatory measures will provide adequate protection to the environment such that, taking into account risks and benefits, there will be no unreasonable adverse effects from the use of pentachlorophenol contaminated with HxCDD and HCB if registrants lower the HxCDD contamination to 1.0 ppm or lower. The process used to reduce HxCDD must not increase HCB or chlorinated dibenzofurans. The rationale and bases for this requirement is discussed in Section VI.A of this PD 4.

The Agency is not stating that a level of 1 ppm HxCDD is not of regulatory concern. This level has been based in part on the availablity and ecomomic feasibility of existing technologies. The Agency is requiring additional data to determine the feasibility of reducing this upper limit further.

Regarding photolytic conversion, Dr. A.J. Dobbs (personal communication, March 12, 1984) has conducted a study which shows that sunlight does not significantly increase the HxCDD content of pentachlorophenol-treated wood. The Agency will review any additional pertinent data on the subject that come to its attention, but sees no need to seek such data at the present time. The Agency believes that the existing data on pentachlorophenol, HxCDD, HCB and chlorinated dibenzofurans are sufficient to provide for regulatory decision-making.

Issue #5

In the PD 2/3 (pp. 273-274) the Agency addressed the role of the wood preserving industry as a source of ambient background levels of pentachlorophenol in the environment. The Agency assumed that the amount of ambient pentachlorophenol levels contributed by an industry is related to the amount of the chemical used by that industry. The wood preserving industry uses about 80% of the pentachlorophenol in the United States. The Agency asked the SAP if they agreed with this approach to determine the source of pentachlorophenol in the environment and, if not, could the Panel suggest a feasible/appropriate method of more accurately addressing the question.

The SAP stated that the Agency's reasoning appeared to be sound, but stressed the need for determining the use(s) of the remaining 20% of the pentachlorophenol in the U.S.

Agency Response

In addition to the wood preservative uses of pentachlorophenol, there are also "non-wood" uses, including use as a herbicide, defoliant, mossicide, and biocide. Therefore, the Agency assumes that these uses also contribute to the ambient levels of pentachlorophenol in the environment. The Agency is addressing "non-wood" uses in a separate position document detailing the risks and benefits and presenting proposed regulatory actions to reduce potential adverse effects on the environment, including man, from these uses.

USDA (1981, pp. 9099) summarized the fate of pentachlorophenol in the environment stating that the chemical has been found in air, water, and soil to varying degrees. Its presence may be from direct contamination, degradation of other organic compounds, chlorination (in water), or volatilization into the atmosphere.

Several offices within the Agency are coordinating to keep current with data on the subject. The Agency proposed [48 FR 14514] listing as acutely hazardous the waste from the production and manufacture of pentachlorophenol as well as unused formulations and their derivatives.

The Agency's Office of Solid Waste is collecting and evaluating information on this subject to reduce pentachlorophenol and HxCDD contamination in the environment (air, water, soil). The waste from wood treatment plants using pentachlorophenol will also be addressed in the future.

In this Position Document, the Agency is attempting to reduce environmental contamination of pentachlorophenol by several regulatory measures. Regarding contamination in the air, the Agency is requiring that the consumer Information Sheet (CIS), which will accompany the shipments of pressure-treated wood and will be distributed to purchasers of pressure-treated wood, contain statements advising against interior use of treated wood except for limited uses and then only if a sealer is used. The Agency also is prohibiting application of pentachlorophenol in interiors and is prohibiting the application of pentachlorophenol on logs which are intended for use in the construction of log homes.

With regard to contamination in water, the Agency is requiring in this Position Document that the CIS contain statements advising against the use of pentachlorophenol-treated wood where it may come into direct or indirect contact with public drinking water or drinking water for animals, except for incidental contact such as docks or bridges. The Agency's Office of Pesticide Programs and Office of Drinking Water, and FDA coordinated on this particular issue.

Pentachlorophenol residues have also been found in food and animal feed (USDA, 1981). The CIS advises consumers against use of pentachlorophenol-treated wood in barns where domestic animals may contact food or animal feed. The Food and Drug Administration (FDA) sets tolerances for indirect food additives; therefore, registrants may file a petition with FDA to set tolerances to provide for the safe use of treated wood which may contact food and feed (e.g, silos, food troughs, feed bins). Since the FDA has not set tolerances for this use, the Agency has included in the CIS a statement that pentachlorophenol-treated wood should not be used where the pesticide may become a component of food and feed. The FDA has stated that pentachlorophenol-treated wood with surface residues not exceeding 50 ppm may come into contact with raw agricultural products (e.g., apples and bananas with skins intact) [21 CFR 178.3800].

Any further information that becomes available will be distributed to all Offices within EPA (Office of Pesticide Programs, Office of Toxic Substances, Office of Solid Waste, Office of Drinking Water) and will be submitted to other Federal agencies such as FDA and USDA. Regarding the wood preserving uses of pentachlorophenol, the Agency has determined that the modifications to the terms and conditions of registration as outlined in Section VIII of this document will serve to significantly decrease environmental contamination by pentachlorophenol.

Issue #6

The Agency presented to the SAP the proposed regulatory actions and modifications listed in the PD 2/3 relating to pentachlorophenol. The SAP concurred with the Agency's proposals, but made the following additional recommendations:

- elbow length rubberized gauntlets, not merely gloves, be required for protective clothing.

- closed systems during emptying and mixing operations be recommended rather than required: otherwise, the Agency would be placing an unfair burden on small operators in terms of additional capital investment.

The SAP also concurred on the Agency's proposal to limit application of the pesticides or use of treated wood to outdoors. The SAP did not disagree with the several exceptions for use of treated wood indoors as listed in the PD 2/3, such as all-weather wood foundations, support structures, certain uses of millwork, and wood treated for sapstain control with 0.5% sodium pentachlorophenate.

Agency Response

Regarding use of gauntlets, the Agency has determined, as discussed in the Agency's response to Issue #2 above, that gloves impermeable (90% protection) to the pesticide will offer the applicator protection from hand dermal exposure and that long-sleeved coveralls will offer further protection from dermal exposure in certain use situations.

As discussed in Section VI.C.3 of this PD4, the Agency reevaluated the PD 2/3 proposal that closed systems be required for emptying and mixing prilled or flaked formulations of pentachlorophenol and powder formulations of sodium pentachlorophenate. The Agency has concluded that, in order for the benefits of use to outweigh the risks, closed systems must be used. Protective clothing and respirators reduce exposure, but not to as low a level as the Agency expects if closed systems are used. However, in order for the small treatment plant operator to plan for the financial investment in closed systems, the Agency will provide a 3-year "phase-in" period for treatment plants to install closed systems. In the meantime, protective clothing and a respirator must be worn by applicators.

Regarding the use of treated wood indoors, the Agency requires that pentachlorophenol pressure-treated wood may be used only for laminated beams and building components in contact with the ground and only if properly sealed, as described in the Consumer Information Sheet in Section VII.C of this document. If the Consumer Information Sheet is not adequately distributed by industry such that the public is not sufficiently informed of this requirement regarding use of pressure-treated wood in interiors, then the Agency will promulgate a rule under TSCA to require that this information accompany treated wood.

The Agency is also requiring that labels for home and farm pentachlorophenol and creosote products state "Do not apply in residential interiors." Application of pentachlorophenol outdoors will be allowed. The Agency is prohibiting home and farm application to wood intended for use in residential interiors, except for millwork which has outdoor surfaces and then only if it is sealed. As discussed in Section II.B. of this document, new data submitted by Koppers (Nov. 15, 1983) has indicated than arsenic air levels in homes constructed with arsenic treated wood were measured at 0.004 ug/m^3, a level lower than background air levels in some cities (USDA, 1980). Therefore, the Agency will not restrict the use of arsenic treated wood in interiors, as long as the surfaces are cleaned thoroughly and all dust is removed from the wood.

Issue #7

The SAP stated that EPA should require industry to reduce the dioxin (HxCDD) content of pentachlorophenol to as low a level as is technologically and economically feasible.

Agency Response

The Agency considered (PD 2/3, p. 642) requiring the registrants to reduce the HxCDD contamination in pentachlorophenol and sodium pentachlorophenate from a representative upper limit of 15 ppm HxCDD to 1.0 ppm, but concluded that (1) the benefits of use would outweigh the risks if certain proposed regulatory measures (e.g., protective clothing and equipment, restricted use requirements, prohibition against interior use) were adopted and (2) some companies might cease manufacturing these products due to the costs involved in the production conversion to the purer form.

As fully discussed in Section VI.A. of this document, the Agency has reevaluated its position regarding HxCDD. In light of the SAP recommendation and increased estimated risks since publication of the PD 2/3, the Agency has concluded that it is necessary to set a current upper limit of 15 ppm HxCDD contamination for all technical pentachlorophenol and sodium pentachlorophenate products and to require that registrants reduce this contamination to 1.0 ppm or below within 18 months. The process used to reduce the HxCDD must not increase the chlorinated dibenzofuran and hexachlorobenzene contaminants.

The Agency has concluded that industry must decrease HxCDD contamination in pentachlorophenol and sodium pentachlorophenate to protect the public from unnecessary exposure to this oncogen, that it is economically and technologically feasible, and that this is necessary for the benefits of use to outweigh the risks. Section VIII of this document summarizes the modifications to the terms and conditions of registration which registrants must make and the time frames required for these modifications.

B. Inorganic Arsenicals

Issue #1

The Agency asked the SAP how to determine the species of arsenic in the Taiwanese well-water study (PD 2/3, p. 104) and further asked if pentavalent arsenic will convert in the body to trivalent arsenic if it is absorbed. The SAP stated that there was not sufficient evidence to resolve these questions.

Agency Response

The Agency has received additional information since the time of the SAP's response to indicate that (1) the arsenic in the Taiwanese well-water was 80% pentavalent (As V) (Irgolic, 1982) and (2) if pentavalent arsenic is absorbed, most of it will convert to the trivalent (As III) form (Rispin, 1983), as shown in both *in vivo* and *in vitro* studies.

A study performed in 1979 by Yamauchi and Yamamura provides suggestive evidence that *in vivo* reduction takes place in the human body. In this study, a human subject ingested extract of seaweed containing 86% of the arsenic as arsenate. More arsenite than arsenate was excreted in the urine. *In vitro* studies also support the hypothesis that pentavalent arsenic may be reduced by tissues. Incubations of arsenate with human erythrocytes (Ataullakhanov et al., 1978) and tissue homogenates (Uthe and Reinke, 1975) led to formation of trivalent arsenic.

In a series of experiments, in mice and rabbits, Marie Vahter and colleagues (1983) have proved definitively that arsenate is reduced to arsenite *in vivo*. Not only has arsenite been found in the urine and plasma of mice one hour after dosing with arsenate, but rabbits dosed at very low levels of arsenate excreted 10% of the total administered dose as arsenite in 4 hours.

This new information does not necessitate any change in the Agency's regulatory position on inorganic arsenic because the Agency based its evaluation of the mutagenic and teratogenic potential of inorganic arsenic on studies involving both valence states of the chemical. The two states of arsenic have somewhat similar effects. Similarly, the Agency's Carcinogen Assessment Group based its determination of oncogenicity on epidemiology studies involving populations exposed to both forms of arsenic.

Issue #2

The Agency asked if the SAP agreed with the proposed regulatory actions to reduce risk due to arsenic exposure. The SAP stated that with the additional recommendations it was making in connection with the Agency's proposed regulatory action in the PD 2/3 (see Issue #5 below), the risk from arsenic exposure will be reduced to a satisfactory level.

Agency Response

Though the Agency has modified somewhat the regulatory actions proposed in the PD 2/3 to arrive at the final regulatory position described in this Position Document, the Agency has determined that the risks of use as calculated for this position document will be outweighed by the benefits of use if certain protective measures are required as outlined in Section VIII of this position document. The Agency's response regarding the additional recommendations made by the SAP is discussed in Issue #5 below.

Issue #3

The Agency asked the SAP if additional sampling was needed to determine exposure to arsenic in all-weather-wood-foundations. The SAP stated that additional measurements were not necessary.

Agency Response

As stated above in SAP Issue #6, upon receipt of new data by Koppers (Nov. 15, 1983) which caused the Agency to change the exposure estimate from 0.03 ug/m^3 to 0.004 ug/m^3 arsenic in the air of homes with arsenic-treated wood, the Agency will not restrict the use of arsenic in interiors, as long as surfaces are cleaned and free of dust. The exposure is not significantly different from background (controls).

Issue #4

The Agency asked the SAP if the present teratology and fetotoxicity RPAR "triggers" for the inorganic arsenicals needed to be reconsidered; i.e., did the SAP agree that the inorganic arsenicals meet or exceed the RPAR criteria for teratology and fetotoxicity? The SAP stated though they believed the RPAR criteria did not need to be reconsidered, additional exposure data on the arsenicals are needed.

Agency Response

The Agency has reevaluated the studies on teratogenicity/fetotoxicity and has concluded that although none have been performed according to commonly recognized and currently acceptable methodologies, the teratology and fetotoxicity "triggers" have not been rebutted for the inorganic arsenicals (Sochard, Oct. 24, 1983).

The studies all contain one or more of the following deficiencies:

1. Gavage not continued daily throughout organogenesis.

2. Maternal toxicity not reported.

3. Administration of only one or two dose levels.

4. Absence in any study of one or more of the following: no observed effect levels (NOEL) and lowest effect levels (LEL) for fetotoxicity and maternal toxicity, and for teratogenicity (if the latter is observed).

The Agency has concluded that the protective measures required in this PD 4 will reduce the teratogenic/fetotoxic potential risk from exposure to inorganic arsenicals; there will be an increase in the margin of safety for these effects, (Sochard, Oct. 24, 1983). However, in an action separate from this PD 4, pursuant to FIFRA Section 3(c)(2)(B), the registrants will be required to submit appropriate teratogenicity/fetotoxicity studies in order for the Agency to determine a NOEL for the inorganic arsenicals. After receipt and evaluation of that data, the Agency will take further regulatory action if necessary.

Regarding the SAP's statement for the need for more exposure data on the arsenicals, the Agency reviewed a study by NIOSH (1983) which demonstrated that the level of arsenic to which workers in arsenical treatment plants are exposed was lower than that estimated in the PD 2/3. Also, as discussed in Section II of this document, the Agency assumed that 10 ug/m^3 is the upper limit of arsenic to which workers are exposed over an 8-hour workday and incorporated this in the calculations for risk estimation. The Agency has concluded that workers must wear respirators if the air level of arsenic is unknown or if worker exposure exceeds 10 ug/m^3 averaged over an 8-hour workday.

Issue #5

The Agency asked the SAP to review and comment on the regulatory actions proposed in the PD 2/3 to reduce exposure to the inorganic arsenicals. The SAP concurred with all the proposed actions, but recommended the following concerning arsenic:

- elbow length rubberized gauntlets, not merely gloves, be required,
- closed systems during emptying and mixing operations be recommended, rather than required, for powder formulations of the inorganic arsenicals,
- limiting use of treated wood to outdoors (except for all-weather wood foundations),
- reduction of arsenical residues on treated wood,
- development of a good sealant for outdoor wood treated with arsenic.

Also, the SAP deferred to the Agency's judgment the decision regarding prohibiting use of arsenic-treated wood which is likely to come into contact with food, feed, or potable water.

Agency Response

As discussed in Issue #2 for pentachlorophenol, the Agency has determined that gloves impermeable to the pesticide will offer the applicator adequate protection from hand dermal exposure and that, for pressure-treatment uses, overalls, jackets, and boots will offer adequate protection from dermal exposure other than through the hands. For the brush-on treatments of inorganic arsenicals, gloves and disposable coveralls or other suitable protective clothing must be worn by applicators.

For mixing and emptying operations using powder formulations of the inorganic arsenicals, the Agency has determined that closed systems are required. Without closed systems for mixing/emptying such formulations, the dermal risk is 7.3×10^{-3}, and the inhalation is 4.1×10^{-3}, assuming 10 ug/m^3 arsenic. These risks are considered by the Agency as too high to be offset by the benefits.

Regarding the SAP's recommendation to limit the use of treated wood to outdoors, the Agency has determined that arsenic pressure-treated wood does not pose undue risk when used for All-Weather-Wood-Foundations and other limited uses. This issue is addressed in the model Consumer Information Sheet which is required to be distributed by industry. The model CIS is contained in Section VII.C of this document.

The SAP also recommended that arsenical residues on treated wood be reduced by using clean wood for treatment. The Agency has concluded that arsenical residues will be adequately reduced if applicators are required to adhere to industry standards as defined by AWPA Standard C-1 and AWPB Standards LP 2 and LP 22, discussed in Section VI.C.4 of this document. These standards require that the processes used to apply inorganic arsenical formulations shall leave no visible surface deposits on the wood, i.e., that the treated wood shall not have a surface residue or crystallization. Reducing the surface residues on treated wood will reduce the inhalation and dermal exposure to treatment plant applicators as well as end-users of the arsenical treated wood.

The Agency has no data at the present time on sealants for arsenic treated wood to be used outdoors. As discussed in Section II.B of this PD 4, dermal absorption of arsenic from arsenic-treated wood is expected to be negligible; therefore, the Agency has concluded that sealants are not necessary for treated wood to be used outdoors for picnic tables, playground equipment, and similar items.

The Panel deferred to the Agency on the issue of using treated wood which may come in contact with food, feed, or potable water. The United States Food and Drug Administration (FDA) has advised the Agency that FDA has the authority to issue food additive regulations for residues of the wood preservatives that may become a component of food or feed through contact with treated wood (Heil, 1983). Section VII.A.5.of this document contains a more detailed discussion of this issue. In summary, FDA has issued a regulation setting a safe level of pentachlorophenol and sodium pentachlorophenate in wood which may contact raw agricultural products, but has not issued regulations setting safe levels of the three wood preservatives (including arsenic) which may become a component of food or animal feed (Heil, 1983). Therefore, EPA is requiring that the CIS, which will accompany each shipment of pressure-treated wood, contain the following statement:

> Do not use treated wood under circumstances where the preservative may become a component of food or animal feed.

FDA has indicated they concurred with this statement (FDA, February 2, 1984).

Regarding treated wood which may come into contact with potable water, EPA recommends that a statement be included in the Consumer Information Sheet which would advise against the use of treated wood where the preservatives might come into direct or indirect contact with public drinking water and would advise against the use of pentachlorophenol and creosote treated wood where there may be contact with animal drinking water, except for incidental contact such as docks and bridges. Section VIII.E of this document also contains a more detailed discussion of this issue.

C. Creosote

Issue #1

The Agency asked the SAP if they agreed with the Agency's conclusion that creosote is a mutagen. The SAP stated that they did agree with the Agency's reasoning; i.e., (a) Creosote is a complex mixture exhibiting toxicity as well as mutagenicity: Creosote P 1 and P 2 are demonstrably toxic in microbial and mammalian test systems; and (b) the Ames Test is positive for the mutagenicity of creosote as well as other complex creosote mixtures. [A typical blend of the various creosote distillates for P1 would be solvent naphtha, naphthalene still residue, and uncorrected creosote; for P2, coal tar and uncorrected creosote (USDA, p. 22, 1980).]

Agency Response

The Agency agrees with the SAP's statements confirming that creosote is a mutagen (Anderson, 1983). The Agency has received no data since the publication of the PD 2/3 which would indicate otherwise.

Issue #2

The Agency asked the SAP if the Tabershaw (1980) and Association of American Railroads (AAR)(1979) surveys could be used to substantiate the need for well-conducted epidemiology studies to estimate the oncogenic risk to humans from exposure to creosote and if the information from the surveys could be used in the design of improved studies. The SAP recommended that, in light of the inadequacies of the surveys, EPA conduct additional epidemiological studies to obtain the necessary data. The SAP stated that EPA could use the data in the Tabershaw and AAR studies in the design of improved studies.

Agency Response

The Agency determined, as set forth in the PD 2/3, that creosote is an oncogen. The Agency will follow the SAP's recommendation to take the two surveys into account in the design of further epidemiological studies to estimate oncogenic risk. As summarized in Section VIII of this PD 4, the Agency will require that registrants conduct a retrospective epidemiology study on wood treatment applicators exposed to creosote and submit air monitoring and dermal exposure data on creosote in order to provide a quantitative basis for estimating potential risk to applicators exposed to creosote. For the present, the Agency will allow current registrations of creosote products to continue, with certain modifications as summarized in Section VIII of this document, but will, in an action separate from this PD 4 require registrants to conduct the studies to maintain in effect existing registrations pursuant to FIFRA Section 3(c)(2)(B).

Issue #3

The Agency performed a qualitative evaluation, rather than a quantitative risk assessment for the oncogenicity of creosote. Therefore the Agency asked the SAP if the Agency should ask for rodent inhalation studies using creosote aerosols, epidemiology studies of wood preservative treatment plant workers, and more extensive exposure studies in wood preservative pressure treatment plants where creosote vapor and polycyclic particulate organic matter would be sampled.

The SAP stated that though there are enough rodent data available on creosote, they would recommend additional epidemiological studies of wood-preservative treatment-plant workers and more extensive exposure studies in such plants.

Agency Response

As stated above in the "Agency Response" to Issue #2, the Agency will require registrants to conduct an epidemiology study of creosote treatment plant workers; the study will include air monitoring and dermal exposure data on creosote.

Issue #4

The Agency asked the SAP if they would advise the Agency to seek exposure data to estimate the hazard to workers from exposure to creosote in non-pressure treatment plants. The SAP stated that EPA should seek such information.

Agency Response

As stated in the Agency's response to Issue #2, the Agency will require the registrants to conduct a retrospective epidemiology study in workers exposed to creosote in treatment plants and to provide air monitoring data and creosote dermal exposure data. These data will enable the Agency to perform a quantitative risk assessment for creosote.

If the risks are unacceptably high even after considering the risk reduction afforded by the protective measures outlined in this document (Section VIII), then the Agency will take further regulatory action as appropriate to insure that the benefits of use of creosote outweigh the risks.

Issue #5

In the PD 2/3, the Agency proposed restricting the use of creosote for home and farm use, railroad tie repair, and groundline treatment of poles to certified applicators. The Agency asked the SAP if this proposed restriction was justified in light of the lack of exposure data. The SAP stated that the certified applicator requirement was justified except in the case of farm use where it appeared to be too restrictive and suggested the Agency examine ways to enable farmers with small farming operations to use creosote without becoming certified.

Agency Response

The Agency has determined that the potential risks of oncogenicity and mutagenicity from exposure to creosote are not outweighed by the benefits of use unless registrants modify the creosote labels for home and farm use, railroad tie repair, and groundline treatment of poles to include the requirements for certain protective clothing and to specify use precautions, as outlined in Section VIII of this document. Because of the Agency's continued concern, all formulations of creosote must be classified for Restricted Use.

Issue #6

The Agency recommended promulgating a rule under TSCA which would prohibit interior use of creosote-treated wood. The SAP recommended that EPA examine the possible use of sealants in connection with indoor uses of creosote because industry claims some of the indoor uses are essential in industrial settings.

Agency Response

The Agency followed the SAP's recommendation and has determined that wood pressure-treated with creosote does not pose undue risk when used in interiors of industrial buildings for wood-block flooring and industrial building components which are in ground contact and are subject to decay or insect infestation, but only if two coats of an effective sealer are applied. A statement to this effect is currently contained in the model Consumer Information Sheet, which must be distributed by industry as described in detail in Section VII of this document. The Consumer Information Sheet gives examples of specific sealers which would be appropriate for use in interior settings. The information must be distributed to consumers at the time of purchase of pressure-treated wood.

IV. UNITED STATES DEPARTMENT OF AGRICULTURE (USDA) COMMENTS AND AGENCY RESPONSE

The United States Department of Agriculture (USDA) also responded to the PD 2/3 on the wood preservatives. Their comments are contained in their entirety in Appendix E of this position document. The Agency carefully considered the USDA comments in the development of the final regulatory position.

USDA concurred generally with the Agency's proposal to continue the registration of the wood preservative uses of pentachlorophenol, creosote and the inorganic arsenicals, with modifications to the terms and conditions of the registrations. A summary of USDA comments and the Agency responses to these comments follows.

Issue #1

USDA concurred with the Agency's proposal in the Preliminary Notice of Determination to cancel registrations for pentachlorophenol available for retail sale in concentrations of 5% or less intended for application by a spray method.

Agency Response

In the PD 2/3, the Agency proposed cancelling registrations for pentachlorophenol spray products available for retail sale in concentrations of less than 5% pentachlorophenol. The Agency's goal was to eliminate these products for use by home and farm applicators, but retain pentachlorophenol spray products containing greater than 5% pentachlorophenol for use by Certified Applicators only. The Certified Applicators would, if they so wished, be able to buy pentachlorophenol products which were more concentrated than 5%, mix and dilute them to any concentration they deemed appropriate and then spray these products onto wood. Therefore, the Agency reasoned that the "Ready-to-Use" spray pentachlorophenol products with less than 5% pentachlorophenol were unnecessary. However, the Agency has reevaluated this issue and has concluded that if Certified Applicators wished to spray a pentachlorophenol concentration of less than 5% onto wood, it would be more convenient and safer if they could buy a product already diluted to that concentration. This would eliminate the extra step of mixing and diluting and would thus eliminate the exposure due to possible splashing. Therefore, the Agency has concluded that registrations for pentachlorophenol spray products containing less than 5% pentachlorophenol will be retained, but will be for use by certified applicators only. Protective clothing and respirators will be required to be worn as described in Section VI.E (Home and Farm Uses).

Issue #2

USDA stated its concern that EPA had underestimated the economic impacts that could result if specific uses of the wood preservatives were cancelled or restricted.

Agency Response

The Agency believes that it has taken the considerations of economic impacts into account in reaching its conclusions about continued use of the wood preserving chemicals (Eckerman, 1982). However, the Agency believes that restricted use classification is necessary for all uses of the wood preservatives, except for brush-on treatments of the inorganic arsenicals, in order to assure that they are used by applicators with the requisite training to handle these products properly. Section VIII of this document summarizes the uses of the wood preservatives which will be classified as Restricted Use pesticides.

Issue #3

USDA has suggested that more data are needed on applicator exposure, disposal of treated wood, and residue levels of wood preservatives in water, air, food, and feed.

Agency Response

The Agency is always receptive to additional data pertinent to its regulatory positions, and will consider any data that are submitted bearing on any of the positions taken in this document.

Regarding applicator exposure and disposal of treated wood, the Agency has adequate data (PD 2/3, pp. 263-344, and p. 701, and Section VII.A.3 of this PD 4) to require that certain precautionary measures be taken. There are also adequate data on residues of wood preservatives in water to allow the Agency to prohibit certain uses of treated wood which may come into contact with potable water (Section VII.A.5 of this PD 4).

As previously discussed (Arsenic, Issue #5), FDA issues food additive regulations addressing treated wood which may come into contact with food and feed.

The Agency's recommendations regarding statements which should be included in the Consumer Information sheet regarding disposal of treated wood and possible contact of treated wood with food, feed, and water are summarized in Section VII.C of this position document. The bases for these recommendations are discussed in Sections VII.A.3 (Disposal of Treated Wood) and VII.A.5 (Food/Feed/Water Issue).

Issue #4

USDA commented that respirators are not necessary for applicators who enter arsenical pressure treatment cylinders because the inorganic arsenicals are inorganic salts which have no measureable vapor pressure and do not release arsenic fumes. USDA stated that a dust mask which would prevent inhalation of arsenate particles or mist would be sufficient.

Agency Response

The Agency agrees with USDA that, because there are no arsenic vapors, respirators are not necessary to reduce the inhalation risk for applicators exposed to arsenic "vapors" who enter inorganic arsenical pressure treatment cylinders. However, the Agency has concluded that respirators are necessary to reduce inhalation of arsenic-laden dust particles if the air concentration exceeds a certain level. The Agency assumes that the inorganic arsenic-laden dust level will be no greater inside the cylinder than the level throughout the rest of the treatment plant.

The Agency has adopted a Permissible Exposure Level standard whereby respirators will be required for workers in arsenical plants if the air level of arsenic is unknown or exceeds 10 ug/m^3 averaged over an 8-hour period. The Agency believes that this requirement will be effective in minimizing inhalation exposure of all employees, including applicators who enter cylinders at arsenical plants. The rationale for this determination is described in Section VI.C.1 of this document.

Issue #5

USDA stated that for home and farm applications of creosote or pentachlorophenol which contain concentrations of pentachlorophenol greater than 5%, both certified and noncertified applicators who may be applying the chemical under the supervision of a certified applicator should wear the same protective clothing. USDA further stated that for pentachlorophenol solutions of 5% or less, long-sleeved shirts and trousers offer adequate protection.

Agency Response

The Agency has determined that, in order for the benefits to exceed the risks, home and farm use of all pentachlorophenol and creosote products must be restricted for use by certified applicators only. Section VI.E. of this document discusses the rationale and bases for this determination. Those creosote and pentachlorophenol products classified for Restricted Use must contain label instructions specifying the type of protective clothing (e.g., gloves, disposable coveralls) to be worn by certified applicators and applicators under their direct supervision. Section VIII of this document describes in more detail the protective clothing requirements.

Issue #6

USDA commented that wood preservatives which are used by homeowners and by contractors performing construction for homeowners should not be classified for restricted use because these persons will have relatively limited exposure to the pesticides. USDA questioned whether current certification programs apply to new groups of workers who do not fit into the classification of commercial forestry or farm-oriented certified applicators.

Agency Response

The Agency continues to be concerned about the potential oncogenic and mutagenic effects from exposure to creosote and about the potential oncogenic, teratogenic and fetotoxic risks from exposure to pentachlorophenol. Because the Agency now estimates the dermal absorption rate of pentachlorophenol to be 50% rather than 10% (Section II) and the protection afforded by gloves to be 90% rather than 99% (Section II), the margins of safety for potential teratogenic/fetotoxic effects from exposure to pentachlorophenol have decreased from 560 (PD 2/3) to 12.

The Agency considers a margin of Safety of 12 to be a significant potential fetotoxic risk to pregnant women. Therefore, as described more fully in Section IV.E, all home and farm pentachlorophenol and creosote products will be for Restricted Use only in order for benefits of use to outweigh the risks. The Agency will contact the states regarding this requirement so that they may provide for training home and farm applicators and others in their State Certification programs.

The Agency has concluded, however, that it is not necessary to classify the brush-on arsenicals as a restricted use pesticide. The label will indicate that brush-on treatments with arsenicals are for commercial construction use only. It is only used by carpenters at construction sites to apply to the cut ends of arsenic treated wood and must not be used for household puposes. Section VIII of this document summarizes which wood preservative products will be classified for restricted use. Several sections of this document present the rationale for restricting the use of the various wood preservative formulations.

Issue #7

USDA expressed concern that the Agency's proposed limitations on interior uses of treated wood were too stringent, and would result in the unavailability of treated wood for some uses for which there are no substitutes. USDA commented that exposures can be reduced by effective sealers to a level where the pesticides can be used safely. USDA (1981) submitted data to support that position.

Agency Response

After evaluating the data submitted by USDA on sealers, the Agency recommends that interior use of pressure-treated wood be permitted where exposures to pentachlorophenol or creosote vapors can be reduced to a level such that this use will not pose undue risk. Section VII.A.4 of this position document presents the bases for this recommendation. Appendix B presents the oncogenic risk estimates for pentachlorophenol and arsenic as well as teratogenic/fetotoxic margins of safety for pentachlorophenol. In addition, however, there are also acute toxic effects from exposure in interiors to treated wood. The model Consumer Information Sheet which must be distributed by industry to purchasers of pesticide pressure-treated wood addresses interior use and states that pentachlorophenol-treated wood should not be used in residential, industrial, or commercial interiors with certain exceptions, namely laminated beams and building components which are in contact with the soil and which are subject to decay or insect infestation. However, an appropriate sealer should be applied. The CIS states that creosote-treated wood should not be used in residential interiors, and should only be used in industrial interiors for wood-block flooring and building components in soil contact where they may be subject to decay or insect infestation. However, an appropriate sealer should be applied.

As described above in SAP Issue #3 (Arsenic), the Agency will include statements in the CIS allowing the use of arsenic-treated wood in interiors, as long as the surface is clean and free of dust.

The model Consumer Information Sheet (Section VII.C.) gives examples of the appropriate sealers to be applied for pentachlorophenol and creosote-treated wood.

Issue #8

The Agency's Preliminary Notice of Determination recommended promulgating a rule pursuant to TSCA which would require wood to be labeled with precautionary information. Statements in the labeling information would prohibit application of wood preservatives to wood that will be used in a manner which may result in direct exposure of animals or contamination of food, feed, drinking or irrigation water. USDA has commented that such prohibitions are unnecessarily broad and "could prohibit virtually all agricultural uses of treated wood" and could prohibit the use of treated wood on docks and bridges. USDA commented that available data do not support the contention that these uses will result in significant exposure to the public.

USDA further commented that the restrictions proposed for arsenical treated wood for agricultural uses are inappropriate.

Agency Response

Food/Feed: As previously stated in this section (Arsenic, Issue #5), FDA issues food additive regulations for residues of wood preservatives that may become a component of food or feed through contact with treated wood. Uses of treated wood which contact food and feed could include such items as vegetable stakes, food crates, feedlot bins, or other similar food/feed agricultural uses. FDA has issued a regulation providing that pentachlorophenol and sodium pentachlorophenate may be safely used on wooden articles that are used or intended for use in holding raw agricultural products if the levels do not exceed 50 ppm in the treated wood [21 CFR 178.3800]. FDA has not issued food additive regulations for residues of creosote and arsenic which may become components of food or feed, nor for pentachlorophenol which may become a component of food or feed items (other than raw agricultural products). Therefore, the Agency has included a statement in the Consumer Information Sheet (Section VII.C. of this PD 4) which prohibits the use of treated wood where the pesticide may become a component of food and animal feed. For a more detailed discussion of this issue, see Section VII.A.5 of this document.

Drinking Water: Based on data discussed in Section VII.A.5 of this document, the Agency is requiring that pressure-treated wood (all three wood preservatives) not be used where it may come into contact with human drinking water, and that neither creosote nor pentachlorophenol-treated wood should come into contact with domestic animal drinking water (e.g., water troughs). Use of treated wood, such as for docks and bridges, in incidental contact with human or animal drinking water be allowed. The rationale for these requirements is also discussed in Section VII.A.5. The statements regarding these prohibitions are contained in the sample Consumer Information Sheet (Section VII.C). The issue of possible contact of non-pressure treated wood with human or domestic animals' drinking water is discussed in Section VII.A.5 of this document.

Issue #9

USDA objected to a proposed labeling requirement in the Preliminary Notice of Determination dictating the method to be used to reduce surface deposits on wood treated with arsenical compounds, and favored a labeling requirement that "arsenical treated wood must be visibly clean."

Agency Response

The Agency has evaluated certain industry standards for obtaining clean wood and has determined that surface residues of arsenic will be effectively reduced if the product labels are modified as discussed in Section VI.B.4 of this document. This requirement will ensure that the arsenical-treated wood will be visibly clean.

Issue #10

USDA objected to the requirement proposed in the Preliminary Notice that treated wood be disposed of by on-site burial, and that wood wastes in excess of 1,000 kilograms per site be disposed of in accordance with the provisions of the Resource Conservation Recovery Act (RCRA).

USDA stated that there are over 4,000 bridges on National Forest System lands which utilize treated wood as bridge components, that the total weight of each bridge would exceed 1,000 kg in almost every case, that unusable materials from these bridges are often burned when the bridges are replaced, and that the costs of disposing of this material in approved disposal sites would be significant. USDA further states that the hazards of current disposal methods have not been quantified.

Agency Response

The PD 2/3 (p. 701) stated that if creosote-treated wood is burned, various oncogenic or mutagenic compounds may be formed; if arsenic-treated wood is burned, one of the combustion products is arsenic trioxide ash (a teratogen, mutagen, and oncogen). New information indicates that if pentachlorophenol-treated wood is burned, dioxins (including HxCDD) are produced (Rappe and Markland, 1978; and Jansson and Sundstrom, 1978). Therefore, the Agency has concluded that treated wood should not be burned, unless certain precautions are taken.

The Agency does not currently list treated wood as a "hazardous waste," so its disposal is not regulated under the Resource Conservation and Recovery Act (RCRA). Currently, there is no regulation which addresses disposal of treated-wood in excess of 1,000 kg per month per site. However, the Agency has concluded that, for the reasons listed above, treated wood should not be burned in open fires or in stoves or fireplaces, but should be disposed of "by ordinary trash collection or burial." Burial could be either at the site or in a landfill approved by state or federal regulations. The Agency believes that the disposal of treated wood in this way will not pose unreasonable risk to human health and the environment, because the toxicants of concern are not likely to leach into the environment to any significant degree. See Section VII.A.3 of this PD 4 for a more detailed discussion regarding potential leaching.

The Agency has also concluded that burning large quantities of treated wood from commercial or industrial use (for example, from construction sites) would not pose an undue hazard if the treated wood is burned in commercial or industrial incinerators in accordance with state and Federal regulations. The heat of the fire is expected to be higher than in an open fire or fireplace, resulting in combustion of the toxic chemicals.

Therefore, the Agency requires that statements be included in the CIS which would prohibit burning unless the treated wood was incinerated at commercial or industrial installations in accordance with existing state and Federal regulations. Section VII.C contains a summary of the statements in the model CIS.

Issue #11

USDA expressed concern about the Agency's recommendation to promulgate a rule under TSCA requiring end-use labeling which would advise all persons handling treated wood to wear impervious gloves, and requiring individuals who saw treated wood to wear protective clothing and a dust mask. It characterized such regulations as unrealistic and unenforceable.

Agency Response

The Agency believes that such precautions are desirable to minimize inhalation and dermal exposure to the wood preservatives. Section VII of this document discusses the qualitative and quantitative risks of sawing treated wood. The Agency has concluded that, in order for the benefits of use of treated wood. to outweigh the risks, commercial producers of wood or wood products which have been treated with the wood preservatives will be required to participate in a Consumer Awareness Program (CAP) to alert users of wood preservatives to these and other precautions to be taken in the use of pressure-treated wood through dissemination of the Consumer Information Sheet (CIS) which will accompany each shipment of pressure-treated wood. The model CIS contains, among others, the following statements: "When handling the treated wood, wear tightly woven coveralls and use gloves imperious to the chemicals (for example, gloves that are vinyl-coated). When sawing and machining treated wood, wear a dust mask." The Agency will assess the effectiveness of the CAP after it has been operative for a period of one year. If the CAP is successful, as the Agency expects, in informing end-users of treated wood about handling precautions, a TSCA rule may not be necessary.

V. ANALYSIS OF PD 2/3 AND REVISED PROPOSAL[1] COMMENTS

Fifty-nine respondents commented on the wood preservatives PD 2/3, with a total of 67 separate submissions to the public comment file (30000/28C). Twenty-two respondents commented on the Agency's wood preservative proposal presented at the April 14, 1983, public meeting[1], with a total of 29 separate submissions to the comment file (30000/28C). In total, 88 submissions were received from 81 different commenters. Refer to Table 10 for a list of the issues discussed and commenters.

A. Comments on Risk

1. Creosote

Comment Issue #1: Microbiological assays as evidence of creosote mutagenicity

The American Wood Preservers Institute (AWPI) (36A) judges the *Salmonella* experiments of Simmon and Poole (1978) as unreliable evidence of the mutagenicity of creosote/coal tar because of the contradictory results found by Litton Bionetics, Inc. (1978a, 1978b, 1978c) in the *Salmonella* microsome assay for this complex mixture. The AWPI states that these contradictory results indicate the "inherent weakness" of the *Salmonella* (Ames) assay in predicting creosote/coal tar mutagenicity.

Agency Response:

Simmon and Poole (1978) as well as Simmon and Shepherd (1978) were able to demonstrate in three independent experiments using *Salmonella* with exogenous metabolic activation that creosote/coal tar caused a dose-related increase in frameshift mutations. Recent studies by Bos et al. (1983) confirm these positive findings (Vaughn-Dellarco, 1983). Therefore, the Agency concludes that the results of Simmon and Poole (1978) as well as Simmon and Shepherd (1978) provide acceptable evidence for the mutagenicity of creosote/coal tar in *Salmonella*.

In general, the *Salmonella* test has been effective in the evaluation of many different environmental complex mixtures, such as tobacco smoke condensates, drinking water, soot from city air, fly ash, and other combustion products. One major problem in evaluating the potential mutagenicity of

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[1] The Agency held a public meeting on April 14, 1983 (See FR 13257, March 30, 1983, for announcement of meeting) to give interested persons the opportunity to comment on certain changes to the decision proposed in the Preliminary Notice of Determination (46 FR 13024-13029, February 19, 1981) as set forth in the Position Document 2/3. The comments received have been considered in the development of this final decision and are discussed in detail in this Position Document (PD 4). The final position reflects changes made in response to such comments and further evaluation by the Agency since receipt of the comments.

Table 10. Summary of Comments Submitted to the Wood Preservatives File #30000/28C

Subject	Commenter (Number)
Mutagenic potential of creosote	American Wood Preservers Institute (36A)
Oncogenic potential of creosote	American Wood Preservers Institute (36A)
Creosote respiratory and dermal exposure	American Wood Preservers Institute (36A)
Pentachlorophenol teratogenicity and fetotoxicity	The Dow Chemical Company (32); American Wood Preservers Institute (36B); National Forest Products Association (36B)
Pentachlorophenol bioaccumulation	Friends of the Earth (55, 64 and 70)
Dioxin contamination and related oncogenic risk of pentachlorophenol	American Wood Preservers Institute (36B, and 78); National Forest Products Association (36B)
Pentachlorophenol respiratory and dermal exposure	American Wood Preservers Institute (36B); National Forest Products Association (36B)
Interconversion of arsenate to arsenite	American Wood Preservers Institute (36C); Society of American Wood Preservers (53)
Mutagenic potential of inorganic arsenicals	American Wood Preservers Institute (36C)
Inorganic arsenicals teratogenicity	American Wood Preservers Institute (36C)
Sensitivity of animals and humans to arsenic toxicity	Society of American Wood Preservers (53)
Oncogenic potential of inorganic arsenicals	American Wood Preservers Institute (36C); Society of American Wood Preservers (53)
Inorganic arsenicals PD 1 testimonials as supporting evidence	American Wood Preservers Institute (36C)
Inorganic arsenicals respiratory and dermal exposure	American Wood Preservers Institute (36C)
Benefits of wood preservatives usage	Sentinel Wood Treating, Inc. (2); Gibson-Homans Company (3); Coopers Creek Chemical Corporation (4); Illinois Power Company (5); National Solvent

Table 10. (cont'd) Summary of Comments Submitted to the Wood Preservatives File #30000/28C

Subject	Commenter (Number)
	Corporation (6); Soult Wholesale Company (8); Cedar Fence Distributors Company, Inc. (9); Dries Building Supply Company (11); Sampson Paint Manufacturing Company, Inc. (12); Standard Concrete Products Company (13); Lloyd H. Daub, Inc. (15); Harboro Lumber Fuel Co. (16); Philadelphia Reserve Supply Company (17); C.A. Niece Company (19); GAF Supply Center (21); RAECO Products (22); National Woodworks, Inc. (24); Michlin Chemical Corporation (25A); Missouri Department of Agriculture (28); Carson's Hardware (29); N.Y. Power Pool (30); Consumers Power Company (31); Association of American Railroads (34); Edison Electric Institute (35); Missouri Forest Products Association (39); Detroit Edison (40); Osmose (41); Niagara Mohawk Power Corporation (42); Nebraska Cooperative Extension Service (51); Good-Life, Inc. (58)
Treated wood disposal	Department of the Army (1); Illinois Power Company (5); Association of American Railroads (34 and 71); Edison Electric Institute (35); American Wood Preservers Institute (36F); National Forest Products Association (36F); Iowa-Illinois Gas and Electric Company (50); Portland Cement Association (66)
Protective gloves	Sentinel Wood Treating, Inc. (2); Illinois Power Company (5); National Woodworks, Inc. (24); Association of American Railroads (34); Edison Electric Institute (35); American Wood Preservers Institute (36C, 36F and 78); National Forest Products Association (36F); Detroit Edison (40); Osmose (41); U.S. Department of Energy (44); Iowa-Illinois Gas and Electric Company (50); Nebraska Cooperative Extension Service (51); International Woodworkers of America (68)

Table 10. (cont'd) Summary of Comments Submitted to the Wood Preservatives File #30000/28C

Subject	Commenter (Number)
Protective overalls	Sentinel Wood Treating, Inc. (2); National Woodworks, Inc. (24); Association of American Railroads (34); Edison Electric Institute (35); American Wood Preservers Institute (36B and 36C); National Forest Products Association (36B and 73); Detroit Edison (40); Osmose (41); Iowa-Illinois Gas and Electric Company (50); Nebraska Cooperative Extension Service (51); International Woodworkers of America (68); Association of American Railroads (71)
Protective clothing disposal	Association of American Railroads (34); American Wood Preservers Institute (36B and 36C); National Forest Products Association (36B); Osmose (41)
Leaving protective clothing at treatment plant and cleaning of protective clothing	American Wood Preservers Institute (36C); International Woodworkers of America (68)
Respiratory protective equipment	Sentinel Wood Treating Company (2); Illinois Power Company (5); Kerr-McGee Corporation (33); Association of American Railroads (34); Edison Electric Institute (35); American Wood Preservers Institute (36B, 36C and 78); National Forest Products Association (36C); U.S. Department of Energy (44); Friends of the Earth (64); International Woodworks of America (68); Koppers Company (72)
Animal, food, feed and water contamination due to treated wood exposure	Illionis Power Company (5); Missouri Department of Agriculture (28); Consumers Power Company (31); Association of American Railroads (34); Edison Electric Institute (35); American Wood Preservers Institute (36B and 36C); National Forest Products Association (36B); Missouri Forest Products Association (39); Iowa-Illinois Gas and Electric Company (50)

Table 10. (cont'd) Summary of Comments Submitted to the Wood Preservatives File #30000/28C

Subject	Commenter (Number)
Interior uses of treated wood	American Institute of Timber Construction (10); Structural Wood Systems (14); Roberts Consolidated Industries (20); Missouri Department of Agriculture (28); American Wood Preservers Institute (36B, 36C and 78); National Forest Products Association (36B); Jenson-Wright Corporation (37); Forest Products Association of Missouri (39); Nebraska Cooperative Extension Service (51); Levin (60); Friends of Earth (64 and 70); Portland Cement Association (66); Center for Disease Control (69); Koppers Company, Inc. (89)
Restricted use classification: Home and farm use of creosote	Gibson - Homans Company (3); Coopers Creek Chemical Corporation (4); National Solvent Corporation (6); National Paint Center (7); Soult Wholesale Company (8); Dries Building Company (11); Sampson Paint Manufacturing Compay, Inc. (12); Standard Concrete Products Comapany (13); Lloyd H. Daub, Inc. (15); Hatboro Lumber and Fuel Company (16); Doylestown Lumber and Millwork Company (18); C.A. Niece Company (19); GAF Supply Center (21); RAECO Products (22); Monsey Products (23); Michlin Chemical Corporation (25A); Carson's Hardware (29); G.M. Deck & Sons (45); Ecological and Specialty Products, Inc. (47); Walpole Wood workers (56); and The Reliance Company (59)
Creosote - other	Association of American Railroads (34); Osmose (41); Iowa - Illinois Gas and Electric Company (50)
Pentachlorophenol	Michlin Chemical Corporation (25); Missouri Department of Agriculture (28); Association of American Railroads (34); Osmose (41); Arneson Timber Company (46); McPhillips Manufacturing Company (49); Iowa - Illinois Gas and Electric Company (50); Nebraska Cooperative Extension Service (51)

Table 10 (cont'd) Summary of Comments Submitted to the Wood Preservatives File #30000/28C

Subject	Commenter (Number)
Inorganic arsenicals	American Wood Preservers Institute (36C)
Pentachlorophenol restriction based on active ingredient	American Wood Preservers Institute (36B); National Forest Products Association (36B) Osmose (41)
Labeling	National Woodworks, Inc. (24); Missouri Department of Agriculture (28); Association of American Railroads (34); Edison Electric Institute (35); American Wood Preservers Institute (36A, 36B, 36C 36H, 36I, 36J, and 78); Forest Products Association of Missouri (39); Friends of the Earth (64)
Closed environment for pentachlorophenol and sodium pentachlorophenate treatment plant usage	Michlin Chemical Corporation (25); American Wood Preservers Institute (36B and 78); National Forest Products Association (36B); International Woodworkers of America of Oregon (63) and Washington (68)
Regulation of applicator vs. handler and end-user	Consumers Power Company (31); Osmose (41)
Eating and smoking area	Association of American Railroads (34); American Wood Preservers Institute (36B and 36C); National Forest Products Association (36B)
Classification of selected non-pressure treatment uses	Edison Electric Institute (35); U.S. Department of Energy (44); Association of American Railroads (71)
Regulation of pentachlorophenol on millwork	McPhillips Manufacturing Company (49);
Regulation of pentachlorophenol and soduim pentachlorophenate spray treatment	McPhillips Manufacturing Company (49); Publishers Paper (54); International Woodworkers of America of Oregon (63) and Washington (68)
Agency regulation of selected wood preservatives together	McPhillips Manufacturing Company (49)

preservatives together

Table 10. (cont'd) Summary of Comments Submitted to the Wood Preservatives File #30000/28C

Subject	Commenter (Number)
Alternative wood preservatives	Michlin Chemical Corporation (25 and 25A); Osmose (41); Louisiana-Pacific Corporation (43); Nebraska Cooperative Extension Service (51); Seymour Chemicals, Inc. (52)
Exterior use of treated wood	Portland Cement Association (26); American Wood Preservers Institute (36B); National Forest Products Association (36B)
EPA jurisdiction	Kerr-McGee Corporation (33); American Wood Preservers Institute (36B, 36C 36E, and 36H); National Forest Products Association (36B); U.S. Department of Energy (44)
Poles - groundline treatment	Edison Electric Institute (35)
Support of EPA action	Coopers Creek Chemical Corporation (4); Illionis Power Company (5); National Solvent Corporation (6); Monsey Products (23); Consumers Power Company (31); Walpole Woodworkers (56); Osmose (61); Georgia Department of Agriculture (62); Louisiana - Pacific Corporation (73); McFarland Cascade (74); National Forest Products Association (75); J.G. Baxter Company (76); Koppers Company, Inc. (77); Allied Chemical (79)
Pentachlorophenol risk estimates and recommended use modifications	The Dow Chemical Company (32)
Environmental fate of pentachlorphenol	Friends of the Earth (64); American Wood Preservers Institute (78)
Standards for clean, arsenic-treated wood	American Wood Preservers Institute (36C)

complex mixtures, however, is their toxicity to the test organism. Creosote/coal tar is no exception in that toxicity to Salmonella presents a testing problem. Because of the toxicity of creosote/coal tar, the mutagenic activity was only demonstrable within a narrow concentration range. Responses in the Simmon and Poole (1978) and Simmon and Shephard (1978) studies were roughly linear from approximately 5 to 100 ug/plate. Nesnow (EPA, 1979) also indicated that this heterogeneous mixture is toxic to Salmonella and is technically difficult to study (Vaughn-Dellarco, 1983).

Thus, the contradictory (negative) results reported by Litton Bionetics, Inc. (1978a, 1978b, 1978c) may reflect the difficulties in testing creosote/coal tar. Litton Bionetics, Inc. only evaluated log intervals that covered a large concentration range, and thus could have missed a positive response in their initial 1978 experiments because of toxicity. Also, after a Salmonella retest of the material, Brusick (1978) concluded that creosote/coal tar is mutagenic and that attempts to repeat the negative results originally reported by Litton Bionetics, Inc., were unsuccessful. Brusick (1978, 1981) attributed the negative results in the earlier experiments to the quality of the S9 preparations used (Vaughn-Dellarco, 1983).

Comment Issue #2: Mouse lymphoma studies as evidence of creosote mutagenicity

The AWPI (36A) argued that the experiments of Mitchell and Tajiri (1978) do not demonstrate the mutagenicity of creosote/coal tar in mouse lymphoma cells in vitro because mutagenic activity was found only at concentrations that were toxic.

Agency Response:

The Agency acknowledges that there is debate among investigators who use the mouse lymphoma TK +/- assay as to whether data collected at 10% survival are acceptable for evaluating the mutagenicity of a chemical substance. However, Mitchell and Tajiri (1978) demonstrated a significant ($P < 0.001$) dose related increase in mutagenic response in a study using eight dose points. At concentrations that resulted in approximately 11% - 15% total relative growth, weak mutagenic responses were detected (i.e., approximately a twofold increase in the spontaneous mutuation frequency) (Vaughn-Dellarco, 1983). Consequently, the Agency considers the results of Mitchell and Tajiri as evidence that creosote/coal tar is mutagenic in mouse lymphoma cells when an exogenous source of hepatic metabolic activation was added.

The results in the mouse lymphoma TK $^{+/-}$ assay strongly suggest that creosote/coal tar is mutagenic in mammalian cells in culture. The toxicity of the complex mixture to the cells may mask the mutagenicity of components present at low concentrations, thus the results may underestimate the mutagenic potential of this material. Therefore, the results in the mouse lymphoma TK+/- assay strongly suggest that creosote/coal tar is mutagenic in mammalian cells in culture (Vaughn-Dellarco, 1983).

Comment Issue #3: Extrapolation of creosote mutagenicity bacterial test results to humans

The AWPI (36A) states that it is inaccurate to extrapolate the results from bacterial test systems to conclude that creosote/coal tar is a human mutagen.

Agency Response:

The Agency agrees that it is not accurate to extrapolate directly from bacteria to the likely human response and classify any chemical substance as a "human mutagen." The purpose of in vitro tests, such as the Salmonella assay, is to screen chemicals for their potential mutagenicity and/or carcinogenicity. The Agency's conclusion is that the weight-of-evidence (i.e., positive data derived from in vitro tests in bacteria and mammalian cells as well as data regarding the mutagenic and/or carcinogenic activity of the individual components of creosote/coal tar) suggest that creosote/coal tar have the potential to cause mutations in humans and not that creosote/coal tar is a human mutagen (Vaughn-Dellarco, 1983).

It is recognized that creosote/coal tar was evaluated in in vitro tests only. When evaluating the risk posed by exposure to a mutagenic agent, several factors, including absorption and metabolism, may alter the mutagenic response in a mammal compared to that in in vitro tests. Although in vivo studies in mammals are necessary to better characterize the risk of creosote/coal tar, this does not negate the results from the in vitro studies which do indicate the intrinsic mutagenicity of creosote/coal tar (Vaughn-Dellarco, 1983).

Comment Issue #4: Mutagenic components of creosote do not render the mixture mutagenic

The AWPI (36A) points out that while flaked coal tar pitch and components of coal tar epoxy were shown to be mutagenic in the Escherichia coli WP2 reverse mutation assay, creosote/coal tar was not (Mortelmans and Ricco, 1980). In their view, to assume that the mutagenic components of a complex mixture necessarily render the mixture itself mutagenic is an invalid conclusion.

Agency Response:

The Agency agrees that the mutagenicity of the individual chemical components of a complex mixture do not necessarily reflect the mutagenicity of the mixture as a whole. There may be interactions (e.g., synergisms and antagonisms) among the chemicals in the complex mixture that alter their mutagenic potential. However, this does not negate the concern with effects of the compounds individually because differential absorption of the constituents of complex mixtures may also occur. It should be emphasized that interactions between the compounds in creosote/coal tar have not been characterized in the study by Mortelmans and Ricco (1980). In addition, flaked coal tar pitch and coal tar epoxy are different complex materials and are not representative of the spectrum of chemicals and the amount of the individual chemicals present in creosote/coal tar (Vaughn-Dellarco, 1983).

Comment Issue #5: Nonspecific toxicity as the cause of unscheduled DNA synthesis

The AWPI (36A) pointed out that nonspecific toxicity may have caused the unscheduled DNA synthesis in the human fibroblast diploid cell line WI-38 (Litton Bionetics, Inc., 1978d).

Agency Response:

Toxicity should not cause an increase in unscheduled DNA synthesis. In this WI-38 cell assay, toxicity would be indicated by a depression or lack of ^{3}H-TdR incorporation. Unscheduled DNA synthesis is indicative of damage to DNA, and therefore indicative of potential mutagenicity (Vaughn-Dellarco, 1983).

Comment Issue #6: Lip cancer in fishermen

The AWPI (36A) questions Shambaugh (1935), which reports on fishermen who held tar-soaked needles in their mouths and developed lip cancer, as evidence of the carcinogenicity of creosote/coal tar. The AWPI (36A) cites Spitzer et al. (1975) as evidence that holding a tar-soaked needle in one's mouth does not increase the risk of lip cancer.

Agency Response:

The Agency has reviewed the Spitzer et al. study (1975), and concludes that the absence of definitive exposure data precludes the use of Spitzer et al. (1975) to refute the Shambaugh (1935) study. For example, it is unclear as to whether the Spitzer et al. (1975) fishermen placed needles moist with coal tar and/or coal tar-soaked nets in their mouths. Also, the type of "tar" used in Spitzer et al.'s study is not defined. It seems likely that pine tar or some less toxic tar would have replaced coal tar used as a preservative in Shambaugh's (1935) study by the time of Spitzer et al.'s (1975) study (CAG, 1982).

Comment Issue #7: Coal tar distillates and cancer

The AWPI (36A) cites "Of Mice and Men and Coal-Tar Distillates: A Rebuttal of Popular Presumptions and Dogmas on Cancer Causation" (Poel, 1980) as evidence that there is no increased incidence of skin or respiratory cancer associated with occupational exposure to coal tar distillates.

Agency Response:

Poel (1980) cited mortality studies by Lloyd (1971), Redmond (1976) and Redmond et al. (1979) as epidemiological evidence that worker exposure to coal tar or coal tar distillates was not associated with cancer of the scrotum, skin, or lung; studies by Reid and Buck (1956) as evidence that there was no increased mortality to coking plant employees from lung cancer; and studies by Doll et al. (1965, 1972) which concluded that men exposed to coal carbonization by-products did not experience excess mortality risk from cancer of the lung, bladder, skin, scrotum or other sites.

The Agency has carefully reviewed the studies cited above and and does not concur with the authors' conclusions. The mortality studies conducted by Lloyd (1971), Redmond (1976), and Redmond et al. (1979) may not demonstrate excess risk of skin cancer from coal tar distillates because of the low case-fatality rate of skin cancer. With regard to lung cancer mortality, the Lloyd (1971) and Redmond (1976) studies found no increased lung cancer mortality for the non-oven areas of the coke plant. However, for coke ovens, where exposure to polycyclic aromatic hydrocarbons was believed to be the highest, particularily the top side of coke ovens, there was a significantly increased lung cancer risk. The non-oven areas consisted of the coal handling area and the by-products area. There is little evidence that coal handling produces a lung cancer risk. The decreased risk of lung cancer that was found in the by-products area is unexplained (Rispin, June 14, 1984).

Reid and Buck (1956) failed to adequately define the basic study population. In studying the causes of death during 1949-1954, it is unclear if the study population includes all dying men who were "on the books" in a coke plant during 1949-1954, or only those found through a special 1952 census. If the cohort consisted of workers employed in 1952, and because there was little or no follow up of any of these members, it appears that this study is basically a cross-sectional study of mortality in a conglomerate of several different coke plants. The observed deaths appear to have occurred to members of the study group employed during 1949-1954. Therefore, the number of cancer deaths observed may have been deficient since it was reported by Lloyd (1971) that men were removed from the books after prolonged absence from work. Because there were no follow-ups after 1954, latent effects were not adequately considered. It is not known how the death rates were derived or defined; therefore, it is not clear if they are compatible with the definition the authors used to derive the study population (CAG, 1982).

With regard to the Doll et al. study, the likelihood of detecting a statistically significant elevation in lung cancer deaths given the number of expected lung cancer deaths (number = 2.14) in the study population of by-product workers is less than 0.8 even if the number of lung cancer cases had been elevated 3.5 fold (assuming a Poisson distribution). The likelihood of detecting a statistically significant excess of mortality from bladder, skin, scrotum, and other sites is even less. Skin cancer mortality is a poor indicator of the skin cancer risk from exposure to coal tar distillate products because the case-fatality rate is so low. Finally, there was no control for smoking (CAG, 1982).

Comment Issue #8: Dermal oncogenic potential of creosote and coal tar

The AWPI (36A) claims that the Agency relied primarily on animal studies to evaluate the dermal oncogenic potential of creosote and coal tar because of the unavailability of adequate epidemiological studies. They pointed out that Maugham et al. (1980) completed a long-term follow-up study of persons treated with coal tar medicinals for psoriasis (the Goekerman Treatment) which demonstrates no increased incidence of non-melanoma skin cancer in these patients.

Agency Response:

The Agency has based its qualitative conclusion that creosote is an oncogen on both animal studies and human case studies. The EPA rejects AWPI's position that creosote is not an oncogen based on the Maugham et al. (1980) study to evaluate the dermal oncogenic potential of creosote and coal tar because of methodological deficiencies and because the short duration of the Goekerman treatment (2-4 weeks) is not comparable to an occupational exposure to creosote/coal tar, (e.g., wood treaters).

The Maugham et al. (1980) study population consisted of persons who had undergone the Goekerman treatment for psoriasis, in which 2% - 5% crude coal tar ointment was applied to body areas generally below the head, approximately 2-3 times a day, for 2-4 weeks. In 1979, the authors contacted 305 of the 426 persons (72%) identified as receiving the treatment during the years 1950-1954. The loss of 28% of the study population could have skewed the study results. The Goekerman treatment patients ranged in age from one year to late adulthood, therefore the recall of information by members of the study population who were very young at the time of the study would not be expected to produce reliable data (CAG, 1982).

The incidence rates used to calculate the expected number of skin cancer cases were derived from medical record abstractions and from 1970 census data for four geographic areas of the United States. Comparing incidence rates derived by abstracting medical records to rates derived by survey people surveyed for disease incidence may not report that they ever had skin cancer. In analyzing the data, Maugham et al. (1980) compared the number of nonmelanoma skin cancers among persons who had undergone the Goekerman treatment with the number that would have been expected had the patients lived in four different geographic areas of the United States. This resulted in an incidence of cancer among the study group which was higher than expected for three of the four comparison areas. The authors concluded, however, "that because the study group was a varied group geographically, there would seem to be no significant increase from the reported incidence figures." The Agency does not concur because of the potential biases indicated above and because there was no adjustment by geographic areas of the incidence rate (CAG, 1982, and Rispin, June 14, 1984).

Comment Issue #9: Skin carcinoma due to creosote/coal tar exposure

The AWPI (36A) cites a study dealing with industrial disease benefits (Lederer and Phillips, unpublished) as evidence that creosote/coal tar exposure does not lead to an excess incidence of skin carcinoma among workers exposed to coal tar and coal tar products.

Agency Response:

The Agency has reviewed the Lederer and Phillips (unpublished) report which is a comparison of the incidence of squamous cell carcinoma among

United Kingdom workers in "coal tar-related industries" to the incidence of squamous cell carcinoma in England and Wales. The Agency finds that it cannot agree with the report's analysis because of invalid statistical methodology concerning incidence rates. By definition, for a disease incidence rate, those people qualifying as the population must also qualify as potentials for the actual cases. However, in this study, the squamous cell carcinoma cases were identified for the year 1973, the worker population represented the year 1977, and the incidence rate included industrial classifications which apparently differed with the employment categories used to derive the prescribed disease data.

A comparison of incidence rates for United Kingdom (Ireland, Scotland, Wales and England) workers in coal tar-related industries to population incidence rates for England and Wales may be biased if the incidence of skin cancer in England and Wales is substantially different from that of the United Kingdom. Comparison of incidence rates among any working population with population rates may also be a biased comparison because of the "healthy worker effect." For example, persons who develop skin cancer or precancerous lesions from working with coal tar materials may change occupations or drop out of the working population altogether. Also, the comparison of a squamous cell carcinoma crude incidence rate for the coal tar-related industrial workers and for the general population is biased because the age distribution of a working population is considerably different from that of the general population (CAG, 1982).

Finally, the comparison of incidence data derived from disease benefit awards with incidence data for the population is also a biased comparison because the disease benefit award is a selective process and population incidence data are not selective (CAG, 1982). Therefore, no conclusions can be drawn from the Lederer and Phillips (unpublished) study about the incidences of skin carcinoma among workers exposed to coal/coal tar products.

Comment Issue #10: Increased risk of skin, bladder or lung cancer due to creosote exposure at wood treatment plants

The AWPI (36A) cites Flickinger's (1980) conclusion that creosote exposure at wood treatment plants did not increase the risk of skin, bladder, or lung cancer. Flickinger based his conclusion on the Tabershaw Occupational Medicine Associates' (1980) health study of wood treatment plant workers.

Agency Response:

This industrial hygiene report (Flickinger, 1980) provides some indication as to the amount of benzene-soluble material and different polycylic constituents of creosote and coal tar to which wood treaters are exposed. However, the report provides no indication of the carcinogenic risk that such exposure may present (CAG, 1982).

The Agency carefully reviewed the Tabershaw Occupational Medicine Associates (1980) cross-sectional health examination survey of workers at five work treatment plants and cannot agree with the conclusion because of several analytical problems.

The population examined (329) is not large enough to assess the effect of creosote exposure on cancer prevalence. If the U.S. prevalence rates for skin cancer (National Center for Health Statistics or NCHS) used by the authors for comparison were used to calculate the expected number of cases, it would have required as much as a 2.9-fold increase over the expected in order to detect a $P < 0.05$ difference (statistical power = 80% probability) (CAG, 1982).

Blacks experience very little skin cancer, and blacks comprised 46.5% of the total plant population. Therefore, the comparison of a skin cancer rate from the NCHS prevalence statistics to the observed skin cancer rate in the study population would be a biased comparison that would underestimate a skin cancer risk if it was present (CAG, 1982).

Although a cross-sectionally-designed study will assess current problems at the treatment plants, workers who have skin cancer may have left the plants. The study population did indicate significant ($P < 0.05$) increases in benign growths, a condition which sometimes is a precancerous lesion. There was also a significant elevation of pseudofolliculitis in the study population. These eruptions were located in areas where clothing rubbed against the skin rather than in sun-exposed areas, which suggests that this effect is a result of the preservative and that workers are being exposed to creosote through their clothing (CAG, 1982).

Cancer latency, or the time from carcinogen exposure to cancer development, may be as long as 25 years. Seventy percent of those examined in the Tabershaw Study had worked 10 years or less in the treatment plants. Only 13% of the study population had between 10 and 15 years of exposure, while 6% of those in the study group had worked between 15 and 20 years in the plants. The majority of workers that were exaxmined by Tabershaw Occupational Medicine Associates had probably not been at the treatment plants long enough to develop cancer, if exposure to creosote is, in fact, a risk factor for skin or other types of cancer (CAG, 1982 and Rispin, June 14, 1984).

There is no indication in this study whether those that were examined were actually exposed to creosote and coal tar. It is expected that some of those examined were office workers and would have had little contact with the preservative. The inclusion of such persons in the study population would have reduced the prevalence rates of skin cancer or precancerous lesions if creosote and coal tar were increasing the risk of skin cancer among treatment workers (CAG, 1982).

Comment Issue #11: Creosote and lung cancer among roofers

The AWPI (36A) states that the excess lung cancer mortality among roofers in the Hammond et al. (1976) study is probably attributable to smoking rather than to exposure to coal tar and asphalt. The AWPI (36A) also suggests that because only five skin cancer deaths were recorded among the 5,939 roofing workers, the incidence rates of skin cancer among the roofers and the general population are not significantly diferent.

Agency Response:

Sterling and Weinham (1976) noted that, based on the National Center for Health Statistics Health Interview Survey (HIS) of 1970, 72% of roofers and slaters are reported to smoke while only 45% of males aged 45 to 61 are reported to smoke. The number of roofers and slaters surveyed was only 36. While smoking may be more common among roofers and slaters than in the general population, the results from such a small sample size would not necessarily invalidate the conclusion of Hammond et al. (Rispin, June 14, 1984).

Also, the number of skin cancer deaths among the roofers was more than expected, which is contrary to what the AWPI (36A) has implied. Among roofers who belonged to the union for 9-19 and 20 or more years the mortality ratios for skin cancer were 4.65 and 4.00, respectively. These ratios are based on small numbers, however, and are not statistically significant (CAG, 1982).

Comment Issue #12: Creosote animal oncogen studies

The AWPI (36A) states that EPA persists in maintaining in the PD 2/3 that creosote and many component chemicals have been well characterized as carcinogens in laboratory animal studies (PD 2/3, p. 85). The AWPI (36A) reiterates its PD 1 rebuttal criticism of EPA's animal oncogen studies and maintains that these studies are indeterminate, inapplicable to humans and irrelevant in light of overwhelming modern epidemiological evidence.

Agency Response:

As stated in the PD 1, the animal studies presented show tumor production following dermal and inhalation exposure to coal tar (Fed. Register, 43 FR 48154, Oct. 1978). The Agency has also presented in the PD 2/3 numerous laboratory animal studies which demonstrate an unequivocal correlation between creosote exposure and animal carcinogenesis. The Agency has cited various human case reports implicating creosote as a human carcinogen. Moreover, various chemical components of creosote such as benzo(a)pyrene, benzo(a)-anthrancene, quinoline, and many others are known carcinogens (PD 2/3). These data provide an overwhelming qualitative assessment of the inherent hazard associated with creosote exposures (CAG, 1982).

For an analysis of the creosote epidemiological studies see Comment Issues #6 through #11.

Comment Issue #13: Treatment plant creosote/coal tar inhalation exposure and risk

The AWPI (36A) claims that there are certain inaccuracies regarding the Agency's determination of potential inhalation exposure for creosote/coal tar pressure treatment workers (PD 2/3, p. 68-74). The AWPI (36A) reiterates the EPA's statements in the PD 2/3 that insufficient data exist to accurately evaluate creosote inhalation exposure. AWPI (36A) states the probable range of ambient air concentration of creosote particulates is estimated by the EPA as 45-95 ug/m^3.

The AWPI (36A) states that the inhalation monitoring studies, cited in Volume III of AWPI's rebuttal to PD 1, establish anticipated levels of specific constituents in the treatment plant workers' breathing zone. Based on data AWPI (36A) resubmitted (AWPI PD 1 Rebuttal; Volume III, Section 2) and additional data (AWPI, 1981 (36A), Table II), the concentration of total particles in the breathing zone range from 20-9,000 ug/m^3.

In response to the Agency's PD 2/3 contention that sufficient data are unavailable to identify specific constituents in airborne particulates in treatment plant workers' breathing zone, the AWPI (36A) states that only benzo(a)pyrene is generally recognized as carcinogenic, and, if fluorene, whose vapor pressure is higher than benzo(a)pyrene1/, is difficult to detect in wood treatment atmospheres, benzo(a)pyrene would be undetectable with available air monitoring techniques.

Agency Response:

The Agency agrees that the submitted data (36A) indicate a higher range of variability and accepts the higher estimate of 20-9,000 ug/m^3 (Day, March, 1982; Day, December, 1983).

Although the benzene-soluble components of creosote contain many different compounds of variable concentrations which preclude an accurate risk estimation, the positive results of the animal oncogenicity studies, listed in the PD 2/3, (page 40, table II, B-1) cannot be disregarded and provide an adequate basis for a regulatory decision (CAG, 1982).

1/ Estimated vapor pressure of benzo(a)pyrene and fluorene at ambient temperature equal .3 x 10^{-6} mm and 1 x 10^{-2} mm, respectively (AWPI, 1981).

Comment Issue #14: Creosote dermal exposure

The AWPI (36A) contends that the NIOSH study of roofers (NIOSH, 1977) (cited in the PD 2/3), which mentions skin sensitization, burns, conjunctivitis and eye irritation as evidence of occupational dermal exposure to creosote/coal tar, has no relation to exposure of creosote/coal tar wood treating plant workers because the materials to which they are exposed are different. Roofers are exposed to pitch and asphalt while wood treatment plant workers are exposed to creosote/coal tar.

Agency Response:

Creosote, pitch and asphalt are a mixture of various hydrocarbons. Creosote is the distillation product of coal tar (NIOSH, 1983); pitch a distillation residue of organic materials, especially tars; and asphalt, a residue in petroleum or coal tar refining. While the similarity of the derivation of these three substances suggests that roofer exposure to pitch and asphalt is similar to treatment plant worker exposure, the Agency is not using this study as support for its regulatory decisions.

Comment Issue #15: Creosote exposure due to railroad crosstie and poles groundline application

The Association of American Railroads (34) contends that no long-term carcinogenic effects from creosote usage have been recorded in the railroad industry; the machinery employed reduces exposure to a minimum.

Osmose (41) expects that exposure due to poles-groundline treatment is minimal since the actual application process is a small percentage of total inspection and treatment time.

Agency Response:

The Agency agrees that because railroad crosstie wood treatment is by remote control, such equipment would reduce exposure, when compared to applying creosote by other methods such as spray or brush-on. However, the applicator may also be involved in loading, maintenance and cleaning, and mixing and/or diluting, which provides an opportunity for exposure. The Agency has concluded, therefore, that railroad crosstie applicators must be certified or work under the direct supervision of a certified applicator. Protective clothing will also be required for applicators, as described in Section VI.E of this document.

Once dermal contamination occurs during wood treatment processes such as poles-groundline application, the exposure persists until the contaminated skin surface, have either absorbed the chemical or been washed free of the chemical. Therefore, the Agency is concerned about the actual exposure which could occur during poles-groundline application and not the length of treatment time.

2. Pentachlorophenol

Comment Issue #1: Pentachlorophenol teratogenicity - evidence of reproductive effects

The Dow Chemical Company (32) questions the Agency's use of data concerning "decreased litter size" (Fahrig et al., 1978) to provide supporting information on pentachlorophenol reproductive effects when the Agency has also concluded this observation (on litter size) should only be considered as an ancillary comment.

The Dow Chemical Company (32) also states that the degree of dilation of renal pelvis observed in fetuses treated with HxCDD (Schwetz et al., 1973) was consistent with retardation of kidney development (a reversible effect). Thus, HxCDD should not be considered teratogenic on the basis of its effect on the developing kidney (The Dow Chemical Company, 32).

Agency Response:

The Agency maintains that taking the Schwetz et al. (1973) study into account, regardless of Fahrig et al. (1978), establishes the teratogenicity of HxCDD. That is, the reversibility of dilated renal pelvis can be properly ascertained only upon postnatal examination, particularly for hydronephrosis, an irreversible effect with which dilated renal pelvis may be associated. Postnatal data were not included in the Schwetz et al. (1973) study. However, production of cleft palate (47% at 100 ug/kg/day) is evidence of HxCDD teratogenicity (Van Ormer, 1982a).

The Agency reiterates the comment that "decreased litter size" is an ancillary issue and has not used this data in developing the current regulatory position.

Comment Issue #2: Pentachlorophenol teratogenicity/fetoxicity - choice of proper NOEL

The Dow Chemical Company (32), the American Wood Preservers Institute (AWPI) (36B) and The National Forest Products Association (NPFA) (36B) contend that EPA's reduction of the pentachlorophenol NOEL from 5.8 mg/kg/day (Schwetz et al., 1974) to 3.0 mg/kg/day (Schwetz et al., 1978) is unjustified. These commenters state that the data used to establish this fetotoxicity/teratogenicity NOEL utilized pentachlorophenol which varied in purity from one set of animal data to the other; they argued that data based on "purified" pentachlorophenol are not relevant to regulation of commercial pentachlorophenol. Although Schwetz et al. (1978) indicate a NOEL between the two doses of 3.0 and 30.0 which were tested, the Agency has identified 3.0 as the proper NOEL.

Agency Response:

The Agency considers all relevant available data. Purified pentachlorophenol data are not irrelevant to the regulation of commercial pentachlorophenol. Because the Agency is not aware of any teratogenicity study conducted according to Agency guidelines on any current commercial pentachlorophenol, such data provide the only basis for regulation.

The provisional NOEL value of 3.0 mg/kg/day was chosen from a one-generation reproduction study (Schwetz et al., 1978), which reports a trend toward decreased neonatal weight at 3.0 mg/kg/day of purified pentachlorophenol, which is consistent with the effects produced by the 30.0 mg/kg/day dosage, but is not statistically significant at 3.0 mg/kg/day (Van Ormer, 1982b). A thorough discussion of the Agency's rationale for the selection of a NOEL value of 3.0 mg/kg/day is presented in the PD 2/3 (pages 347-353).

The teratogenicity study of Schwetz et al. (1974) is inadequate to establish a fetotoxicity NOEL for either the commercial or purified pentachlorophenol. There was a statistically significant increase in skull bone delayed ossification at the lowest tested dose of purified pentachlorophenol (5 mg/kg/day). The study also lists increased incidence of delayed skull ossification at the low dose (commercial grade pentachlorophenol, 5.8 mg/kg/day); lumbar spurs (commercial and purified pentachlorophenol at 5.8 and 5.0 mg/kg/day, respectively); and anomalous sternebrae (purified pentachlorophenol, 5.0 mg/kg/day). Also, the commercial grade pentachlorophenol produced some exencephaly (dose and incidence not listed) which was reported in a public meeting as not significant (Van Ormer, 1982a).

Comment Issue #3: Pentachlorophenol - concern for the fetus in utero

The Dow Chemical Company (32) disagrees with the Agency's PD 2/3 p. 257 contention that, from a regulatory standpoint, a fetotoxic effect may represent as unacceptable a risk to the human fetus as would a teratogenic effect.

Agency Response:

The Dow Chemical Company's (32) claim concerning the difference between reversible (fetotoxic) and irreversible (teratogenic) effects would mandate a difference in the required margin of safety for the two effects, and implies that fetotoxic effects have been shown to be reversible based on adequate postnatal observation. The claim also implies that data exist on the relative variability of the thresholds for these two types of effects. The Agency is not aware of data on pentachlorophenol which show either the reversibility or the variability of the measured fetotoxic effects, which (in any case) could appear in another species as a different type of functional or behavioral deficit, e.g., retardation. Above all, the Agency has concern for health of the embryo and fetus in utero, as well as concern that no reversible or irreversible effects manifest after birth (Van Ormer, 1982a). Therefore, a fetotoxic effect may represent as unacceptable a risk to the human fetus as would a teratogenic effect.

Comment Issue #4: Pentachlorophenol fetotoxicity/teratogenicity margin of safety

The AWPI (36B and 36F), the NFPA (36B and 36F) and the Dow Chemical Company (32) state that the EPA's requirement for a fetotoxic margin of safety (MOS) of 400 is unsupported and excessive. They argue that there are data available on the reversible nature of the fetotoxic effects of pentachlorophenol; they claim that it is highly unlikely that any fetotoxic effects would be evidenced if permissible exposures were limited to one-tenth of the NOEL. Without submitting pentachlorophenol postnatal data, the commentors reiterate the claim that fetotoxic effects such as delayed ossification found in Schewtz et al. (1974) can be reversible. An MOS as low as 100 is suggested as appropriate.

Agency Response:

The assignment of an acceptable MOS is largely a risk/benefit question. A fetotoxic effect such as delayed skull ossification (reversible or irreversible) is merely the indication of an effect in one species (A) which may extrapolate in another species (B) into another type of effect, such as retardation. In the field of teratogenicity, there is a relative lack of ability to make qualitative extrapolations. Since the type of response in species (B) cannot easily be predicted, regulation must be based upon the absence of fetotoxic effects in the species in question (A) by applying an MOS which reflects this lack of qualitative correspondence between species, (i.e., by applying a margin of safety which includes components for both qualitative and quantitative uncertainty.) The Agency is unaware of any pentachlorophenol data bearing on the reversibility of effects such as delayed ossification or dilated renal pelvis (Van Ormer, 1982a).

The Agency did not require an MOS of 400 for fetotoxic effects in the PD 2/3 for pentachlorophenol. The measures proposed in the PD 2/3 to reduce the oncogenic risk from pentachlorophenol to an Agency-acceptable level would provide "margins of safety greater than 400 for fetotoxicity." The assignment of an acceptable MOS must be determined on a case by case, use by use basis by weighing risks and benefits.

Comment Issue #5: Pentachlorophenol bioaccumulation

Friends of the Earth (FOE) (55, 64, 70) contends that there is widespread pentachlorophenol exposure and subsequent blood, urine, semen and sperm cell contamination of pentachlorophenol in humans. FOE states that eighty-six percent of Americans have pentachlorophenol contaminated urine and that pentachlorophenol has been found in the semen and sperm cell of the average male and bioaccumulates in the sperm cell at a level 20-40 times higher than semen. Based on Dougherty et al. (1980), FOE contends "there appeared to be good reason [from the data] to believe that penta causes a reduction in sperm counts." Moreover, FOE further contends that there has been a trend showing decreased sperm counts in American males over the years.

Agency Response:

The Agency has carefully reviewed the study by Dougherty et al. (1980) and finds that it cannot concur with the report's analysis due to uncertainties in interpretation. Dougherty et al. (1980) compares the sperm densities to toxicant residues (in the participants' semen and sperm cells) obtained in a negative chemical ionization screening procedure, for a group of 132 college-aged males. Residues were obtained for a number of unknown polychlorinated substances, as well as polychlorophenols, polychlorobiphenyls, hexachlorobenzene, DDT metabolites, and polychloronaphthalenes. Multiple linear regression1/ was used in an attempt to correlate toxicants uncovered in the negative chemical ionization screening to sperm density. Among the nine tabulated toxicants, the polychlorobiphenyls uniformly gave negative correlations with sperm densities. The overall resultant correlation coefficient for all toxicants was reported as 0.52, which would indicate, according to the report, that the toxicants account for roughly 27 percent of the variance in sperm density distribution. Therefore, there does appear to be an association between sperm density and some of the polychlorinated toxicant residues (Heath, March 16, 1982).

However, the analysis presents uncertainties in interpretation: 1) concentrations of toxicants were not reported, 2) original, individual data were not presented, so that the nature of the distribution and the possibility of extreme values can not be determined, 3) tabulated statistics are not adequately specified as referring to individual or collective toxicants, 4) several statistical assumptions are made (e.g., that no association exists among any of the variables being used in the analysis to explain variation in sperm density) and 5) the contribution of each toxicant to sperm density variation can depend upon the ordering of these variables in the regression equation (Heath, March 16, 1982).

From the format of data presentation and description of data in the study, there is no apparent association (within reasonable significance, stated in the study as 0.01) between the sperm density and the occurrence of pentachlorophenol in study subjects' seminal fluid (Dougherty et al., 1979; Table 2) (Van Ormer, Sept. 22, 1983).

The Agency disagrees with FOE's contention that sperm density data demonstrate a density decrease in the general population during the past 30 years. There are no data on sperm densities in a random sample of the general population. Knowledge of sperm densities is based almost entirely on clinical data for males from infertile marriages and fertile males prior to vasectomy. There are limited data for volunteer groups as in Dougherty et al. (1980), but such groups are not random samples from the general population (Heath, 1983).

Comparisons of the arithmetic means of sperm density distributions can

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1/ Regression analysis is a statistical procedure for expressing in equation form, ($Y = a + b X, + bX_2 ... bX$) the relationship between a dependent variable (Y or sperm density) and independent variables (X_1 X_2....Xn or (the toxicant concentrations) associated with the dependent variable (Heath, March 16, 1984).

be misleading, as pointed out by MacLeod and Wang (1979). Because such distributions are typically skewed to the right, occasional especially high densities can increase the mean considerably, whereas the median is not affected by such values and should be included in such comparisons. A more meaningful approach compares the frequencies (percentages) of counts by sperm density categories, usually in increments of 20 million per ml (MacLeod and Wang, 1979). Densities below 20 million per ml are considered to constitute oligospermia and are of particular importance (Heath, 1983).

Review of the first two sperm density references used by Dougherty et al. (1980) (Macombre et al., 1929 and Hotchkiss et al., 1983) revealed conditions that properly negate the use of either reference to demonstrate a secular decrease in density. The Macrombre mean density and graphic presentations are reportedly based on 271 donors; however, the graphic presentation, intended to portray a frequency distribution of sperm densities, is based on only 223 donors. There is no explanation for this discrepancy, and there are no tabular data to determine the 48 excluded values. The data of Hotchkiss et al. are for 200 fertile males comprising two sets of 100 each. Data for one set (Group 1) were provided by the New York University College of Medicine, Department of Obstetrics and Gynecology; data for the other set (Group 2) were from the New York Hospital, Cornell University Medical College. Comparison of the frequency distributions for the two groups, and of the medians calculated from these distributions, indicates that the two sets of data are statistically different ($P<0.05$). The estimated median density for Group I is 69 million per ml and that for Group II is 106 million per ml. The Group I median is well within the range of medians of various post-1950 data sets (Heath, 1983).

Probably the most comprehensive data for examining the hypothesis of a general decrease in sperm density during the past 30 years are provided by MacLeod in his data on 10,000 males from infertile marriages. His median value for 1,000 such males, published in 1951 (MacLeod and Gold), was 74 million/ml, representing specimens collected during a 1-year period in the late 1940's. Macleod's median values for nine sets of 1,000 specimens each, collected sequentially from 1966 to 1977, are 77, 74, 74, 74, 72, 74, 85, 88 and 71 million per ml (Macleod, 1979). Indeed, there is no suggestion of a secular trend during the past 30 years in the total MacLeod data (Heath, 1983).

James (1980) evaluated sperm density data from 17 papers published from 1934 to 1979 to demonstrate a secular reduction in reported counts of fertile men. He fails to consider, however, that MacLeod's counts from 1969-1977 of 7,000 males from infertile marriages are significantly higher ($P<0.05$) than counts of fertile men, by five authors, used in the James analysis (Heath, 1983).

Review of more than 20 sets of data from the literature spanning the past 40 years demonstrates no clear substantiation of an overall decrease in sperm density. MacLeod and Wang (1979) also contend that such a reduction has not been demonstrated (Heath, 1983).

Comment Issue #6: Pentachlorophenol oncogenicity and dioxin contamination

The AWPI (36B) and the NFPA (36B) claim the EPA's contention that technical pentachlorophenol presents an oncogenic risk due to hexachlorodibenzo-p-dioxin (HxCDD) and hexachlorobenzene (HCB) is incorrect. The AWPI (36B, 78) and the NFPA (36B) remark that pentachlorophenol does not contain the 2,3,7,8-TCDD dioxin, most frequently associated with adverse human health effects; and pentachlorophenol's toxic effects are manifested before any such evidence from HxCDD's presence, so that regulatory measures for pentachlorophenol will prevent HxCDD exposure.

AWPI (36B) further contends that the oncogenic risk analysis should be adjusted for the Science Advisory Board's (SAB)(1978) report that 25% of total HxCDD is comprised of isomers most likely to promote tumors. AWPI (36B) and NFPA (36B) comment that typically the HxCDD content in technical pentachlorophenol is well below the 15 ppm listed in the PD 2/3.

The AWPI (36B) and the NFPA (36B) also contend that the EPA's use of the one-hit model to determine the carcinogenicity of HxCDD based on the National Cancer Institute (NCI) gavage assay (1980) is inappropriate because HxCDD is a "promoter" rather than an "initiator" of cancer. They further comment that Schwetz et al. (1978) and other investigators, including Kimbrough and Linder (1978), indicate pentachlorophenol is not an oncogen; any oncogenic potential of HxCDD is through tumor promotion, not initiation. Thus, any HxCDD-related carcinogenic activity would operate through a dose-response mechanism, i.e., the greater the toxic dose above the no-effect level, the greater the promotion response. In addition, they claim the absence of positive epidemiological data, together with negative animal test results, support the "promoter" conclusion (AWPI, 36B and NFPA, 36B).

Agency Response:

The regulation of both pentachlorophenol and HxCDD is necessary because both pentachlorophenol and HxCDD exposure can cause acute and chronic toxic effects (PD2/3, pp. 247-367). The oncogenic risks associated with HxCDD exposure have been estimated in this PD 4 (Appendix B) to be of the order of magnitude of 10^{-3} based on 15 ppm HxCDD in technical pentachlorophenol even with the protective measures required. Because the required protective measures (e.g., gloves, protective clothing, respirators, etc.) which reduce the acute toxicity and potential teratogenic/fetotoxic risks from pentachlorophenol exposure do not reduce the potential oncogenic risk from long-term exposure to HxCDD to levels where benefits of use outweigh risks, this contaminant must be regulated concurrently and independently. The Agency is requiring an immediate upper limit of 15 ppm HxCDD, a level cited by Rakshpal (1980), SAB (1978), and AWPI (1979) as representative in technical pentachlorophenol, and requiring that this contaminant be further reduced to an upper limit of 1 ppm. The potential oncogenic risk associated with pentachlorophenol results from exposure to the contaminant HxCDD and was discussed in the PD 2/3 (pp. 347-363).

Although HCB has also be shown to be an oncogen in laboratory animals

(PD 2/3, p. 345) the potential risks from the HCB contaminant in technical pentachlorophenol are negligible compared to those of HxCDD. The quantitative oncogenic risk (PD 4) from pentachlorohenol is based on the HxCDD contaminant alone, because the HCB slope (potency) is significantly lower than the HxCDD slope, such that including the HCB-related risk estimate would have only a negligible effect on the total risk. This was also true for the risk estimates calculated in the PD 2/3 (p. 363).

Buser and Bosshardt (1976) report that the forms of dioxins most prevalent in commercial pentachlorophenol are hexa-, hepta-, and octachlorodibenzo-p-dioxins (HxCDD, HpCDD and OCDD, respectively). A small amount of tetrachlorodibenzo-p-dioxin (TCDD) has also been found in pentachlorophenol (Buser and Bosshardt, 1976) but proved not to be the extremely toxic 2,3,7,8-isomer. Because the principle contaminants of pentachlorophenol are the higher order dioxins, the oncogenic potential of pentachlorophenol has been estimated using information which includes the NCI bioassay of 1,2,3,6,7,8- and 1,2,3, 7,8,9-hexachlorodibenzo-p-dioxins (Litt, May 24, 1982).

Although it may be that only 25% of the isomers of HxCDD have been shown to cause tumors in laboratory animals, the Agency assumes, for the purpose of developing regulations, that there may be a structure-function relationship for isomers of the same chemicals and takes a conservative regulatory position in the absence of data to the contrary. The HxCDD oncogenic risk estimate therefore reflects this position; i.e., that 100% of the isomers of HxCDD which are contaminants of pentachlorophenol and sodium pentachlorophenate are potential human carcinogens.

Regarding AWPI's (36B) comment that the HxCDD content is typically below 15 ppm, the Agency received data from several manufactures which indicated that the HxCDD concentration in technical pentachlorphenol could be as high as 23 ppm but was usually approximately 15 ppm. The Agency chose 15 ppm as representative level for purposes of risk estimation in the PD2/3 as well as this position document (PD4). The Agency has received no data on HxCDD to the contrary.

The issue of whether the isomers of HxCDD are promoters rather than initiators is not germane to model fitting. Seven low-dose extrapolation models were used and the one with the best data fit is the multistage model (Litt, May 24, 1982). The multi-stage model has proven to be a more appropriate choice based on mathematical, theoretical and biological grounds (Appendix to Water Quality Criteria Document; November 28, 1980 [45 FR 79318]). Further discussion of the multi-stage model is provided in Section II.A.2 of this document.

The Agency agrees that pentachlorophenol itself has not been shown to be oncogenic in laboratory animals (PD2/3 p. 344), but this does not negate the findings by NCI (1980) that HxCDD, a contaminant in pentachlorophenol, has been shown to cause tumors in laboratory animals. It is the Agency's position that exposure to pentachlorophenol containing HxCDD presents a potential oncogenic risk to humans.

Epidemiological data submitted by AWPI (#81:30000/28C) indicated no increased deaths or cases of cancer occurred from exposure to pentachlorophenol (or inorganic arsenic) in workers at a wood-treating plant in Hawaii. The Agency reviewed these data and concluded the study was inadequate to assess whether a cancer risk existed among the wood treaters (Gibb, 1983). Section V.A.2 (Comment #10) of this PD4 discusses this evaluation more fully.

In the absence of adequate epidemiological data, the Agency continues to assume that pentachlorophenol containing HxCDD poses a potential unreasonable adverse effect. Animal data exist which allow the quantitation of risks and provide an adequate basis for regulation.

A recent reevaluation of the NCI (1980) study showed liver lesions from HxCDD dosed rats confirms that HxCDD is oncogenic in laboratory animals. When compared to historical controls, neoplasia incidence is increased among female rats exposed to the highest dose [NTP (Hildebrant), 1983]. There is a clear indication that liver neoplasia in the female rats was associated with HxCDD exposure (Moore, Nov. 4, 1983). Therefore, based on these findings, the Agency has concluded that technical pentachlorophenol presents a potential oncogenic risk to humans due to the HxCDD that is present. See Section II.A of this PD 4 for a more detailed discussion.

Comment Issue #7: Pentachlorophenol inhalation exposure due to interior use of treated wood

Several aspects of the EPA's exposure analysis for interior use of treated wood are of concern to the AWPI (36B) and the NFPA (36B). These commenters reiterate from the PD 1, that the Agency's assumption of 100% absorption of pentachlorophenol through the lungs is unsubstantiated and based on Thomson and Pavia (1974) and Patty (1978), only 70% of inhaled particles of a 5 micron diameter are retained in the human lung six hours after a single exposure.

The AWPI (36B) and the NFPA (36B) also contend that the Agency's estimated 30 ug/m^3 pentachlorophenol airborne concentration due to interior use of treated wood is an extreme worst case situation. Whitney and Gearhart (1979) and Krause and Englert (1980) have observed concentrations that are one to two orders of magnitude less.

The AWPI (36B) and the NFPA (36B) state that the EPA overlooked the effectiveness of sealants to reduce pentachlorophenol volatilization, including studies (e.g., Thompson, et al., 1979; Ingram, McGinnis and Ferst, 1980), which investigated volatilization reduction for hand-dipped and commercially-treated wood.

The AWPI (36B) and the NFPA (36B) comment that if the Agency were to use 70% absorption and maintain the worst case air concentration estimate of 30 ug/m^3, the MOS for pentachlorophenol would be over 400, an Agency-acceptable level for toxic effects. Based on these statistics, in conjunction with residence-use being less prevalent than storage and farm buildings use, of pentachlorophenol, the proposed severe restrictions are unjustified (AWPI, 36B and NFPA, 36B).

Agency Response:

One hundred percent absorption by the inhalation route does not mean that 100 percent of inhaled material is actually absorbed by the body. Biologically, this is rarely true. The Agency assumed that 100% of inhaled airborne pentachlorophenol was absorbed in determining the pentachlorophenol exposure analysis. This practice is consistent with the Agency's policy of using worst case situations for risk assessments. Toxicologically, an oral dose and an inhalation dose are considered to be equal or totally absorbed by the body for regulatory risk estimations. Determination of the actual absorption of materials by the body can only be assessed experimentally for each specific exposure situation (Zendzian, 1982).

Thomson and Pavia (1974) present results of an experiment in which individuals inhaled "several" 750 milliliter breaths of an aerosol of 5 micron diameter polystyrene particles. It is unclear as to how these experimental conditions relate to pentachlorophenol inhalation exposure. Pentachlorophenol may be in the air as a spray, an aerosol, a vapor, or any combination, which may be inhaled in a single breath, several breaths or continuously. Unlike the solid polystyrene particle, pentachlorophenol is a liquid which can dissolve in the tissue lining the airways and be directly absorbed (Zendzian, 1982).

Data submitted by the AWPI (36B) and the NFPA (36B) (Ingrim and McGinnis, 1980) show that volatilization of pentachlorophenol from treated wood in an enclosed area produces concentrations which vary from the Agency's original estimate. The Agency accepts the AWPI (36B) and the NFPA (36B) comments concerning the effectiveness of sealers in reducing the indoor air concentration of pentachlorophenol from commercially dipped or pressure-treated wood and aged pressure-treated wood (see Section VII.A.4). Freshly treated home application of pentachlorophenol produces concentrations of 34.0-140.0 ug/m^3, industrially dipped pentachlorophenol-treated wood produces concentrations of 4.8-20.4 ug/m^3 while older structures containing pentachlorophenol-treated wood produces concentrations of 0.5-10.0 ug/m^3 (Day, May 19, 1983). The Agency has evaluated these data and has used these levels in the Agency's pentachlorophenol exposure assessment. Refer to Appendix C for the revised pentachlorophenol exposure analysis.

The assignment of an acceptable MOS is largely a risk benefit question and must be determined for each exposure situation. See Comment Issue #4 for further discussion.

Comment Issue #8: Pentachlorophenol inhalation and dermal exposure due to bag emptying and mixing

The AWPI (36b) and the NFPA (36B) state that the Agency's exposure analysis for manual mixing of pentachlorophenol does not support the proposed closed mixing system requirement. The EPA has assumed four hours daily exposure for opening and emptying prilled and flaked pentachlorophenol while, in most cases, a person would not spend more than two hours a day, twice a week at this operation (AWPI, 36B and NFPA, 36B).

The AWPI (36B) further comments that the Agency has used a theoretical maximum exposure projection from powdered pentachlorophenol to calculate inhalation and dermal exposures for mixing while prilled, flaked and granular formulations are used. Using an AWPI/NFPA proposed eight-hour threshold limit value (TLV) of 0.5 mg/m^3 for pentachlorophenol airborne exposure [based on OSHA's established permissible exposure limit (PEL) for occupational exposure to pentachlorophenol of 0.5 mg/m^3], a 70% inhalation absorption (based on Thompson and Pavia, 1974; Patty, 1978), and a two-hour mixing time (see paragraph above), inhalation exposure equals 48.59 ug/kg/day. Dermal exposure calculated with protective clothing equals 6.75 ug/kg/day; the MOS for total exposure (based on a total of 55.34 ug/kg/day) is 105.

The AWPI (36B) and NFPA (36B) also contend that the Agency has failed to take protective gear into account when calculating the risks associated with bag emptying and mixing.

Agency Response:

The Agency agrees that four hours per day for 5 days a week is excessive bag opening/emptying and mixing time. The commenters' values (2 hrs/day for 2 days/wk) were used in revising the inhalation and dermal exposure estimates for bag emptying and mixing of pentachlorophenol in treatment plants (Day, March 26, 1982).

The Agency used the maximum inhalation and dermal exposure projection for pentachlorophenol for mixing powdered, prilled, and flaked formulations, because there are no other data available. The Agency is continuing to rely on these data to estimate upper limit exposure for mixing and empting dry formulations of pentachlorophenol (Day, May 19, 1982). Using the 40 to 400 mg/hr assumption to estimate dermal exposure (PD 2/3, p. 319) for sodium pentachlorophenate should be a more accurate reflection since this chemical is formulated as a powder. The 40 to 400 mg/hr exposure was based on powdered Guthion and powdered fertilizer, respectively.

Inhalation absorption will also remain at 100% (see Comment Issue #7 for explanation). The Agency does not believe that the TLV concept is adequate for pentachlorophenol exposure estimation and will require a "phase in" of closed systems over the next three years for these mixing operations. For a more detailed discussion of this issue, see Section VI.C.3 of this document.

Comment Issue #9: Pentachlorophenol dermal exposure

The AWPI (36B) and the NFPA (36B) contend that because the PD 2/3 states that NCI's dermal bioassay (NCI, 1980) was negative, the Agency should discount all dermal exposure for all use situations (e.g., handling treated wood as well as applying pentachlorophenol) when calculating potential pentachlorophenol carcinogenic risk. The AWPI (36B) and the NFPA (36B) further contend that the Agency recognizes that HxCDD volatilization is unlikely (PD 2/3, p. 338, Table II.D.14) and coupled with the lack of dermal exposure, pentachlorophenol risk would be zero from treated wood end-uses.

The Association of American Railroads (34) claims application equipment for crosstie treatment reduces occupational exposure to a minimum; hence, regulation is unnecessary.

Agency Response:

The Agency has concluded that protective clothing is necessary for those applying pentachlorophenol or handling pentachlorophenol-treated wood. That is, although the NCI dermal bioassay (NCI, 1980) is negative, the dermal absorptions of pentachlorophenol including HxCDD in solvent and sodium pentachlorophenate during the treatment process are estimated by the Agency to be 50% and 1%, respectively (Section II.B). After wood is treated and shipped for use, the solvent is assumed to have volatilized and dermal absorption is reduced to 1%. Likewise, if pentachlorophenol-treated wood becomes wet from rainwater, perspiration or the like, dermal absorption is estimated as 1% (Day, Oct. 27, 1983).

The Agency agrees that an applicator using the automated railroad crosstie equipment would have a decreased opportunity for exposure since the pentachlorophenol applied is by remote control. However, the applicator may also be involved with mixing, diluting and/or loading the wood preservatives into the equipment as well as cleaning and maintaining the machinery. Also, the wind may carry aerosolized or windborne droplets resulting in applicator exposure. The Agency has concluded, therefore, that applicators must be certified or work under the direct supervision of a certified applicator so that through proper training and education the potential for exposure would be reduced. Protective clothing will also be required during application as outlined in Section VI.E.5 (Home and Farm Use/Protective Clothing).

Comment Issue #10: Pentachlorophenol epidemiology study

AWPI (#81) submitted a study by Gilbert et al. (1981) on the effects of chemical preservatives on the health of wood-treating workers in Hawaii exposed to pentachlorophenol and arsenic. AWPI (81) commented that the study concluded that no excess morbidity or mortality that can be attributed to exposure to wood preservative chemicals.

Agency Response:

The study consisted of two parts: a cohort-comparison study and a historical perspective study. The Agency has concluded that the cohort-comparison study which consisted primarily of current workers, was an inappropriate approach to assessing whether a cancer risk existed among wood treaters. There is a good likelihood that persons who develop cancer while working have either died or left employment. In the historical perspective part of the study, the sample size was too small and the follow-up was probably not long enough to have detected an excess risk of cancer. Therefore, because of these limitations, no conclusion can be drawn from this study regarding the potential cancer risks for wood treaters (Gibb, 1983).

3. Inorganic Arsenicals

Comment Issue #1: Interconversion of arsenate to arsenite

The American Wood Preservers Institute (AWPI) (36C) state that the Agency's PD 1 used studies on arsenite (trivalent inorganic arsenic) to reach conclusions on oncogenic, mutagenic and teratogenic effects of arsenate (pentavalent inorganic arsenic) present in wood preservatives, although the PD 2/3 (p.102) states that reduction of arsenate to arsenite in vivo has not been demonstrated with sufficient experimental evidence. Koppers Company, Inc. (72 & 85) also states that a recent review (Woolson, 1983) of studies on arsenic interconversion, including Vahter (undated) and Yamauchi and Yamamura (1979) indicates that arsenate has not been shown to be reduced to arsenite in vivo in man or animal. Arsenite is neither a metabolite of arsenate as defined by 40 C.F.R. 162.3(2) nor is it a "degradation product" as defined by 40 C.F.R. 162.3(1) (AWPI, 36C). AWPI (36C) states that arsenite is oxidized to arsenate in the environment.

The SAWP (53) states that arsenate is reduced to arsenite only under certain conditions. Humans do not reduce arsenate to arsenite; arsenite is found in urine only after an overload, which is not the usual exposure situation. The SAWP (53) further comments that if one acknowledges the EPA contention that arsenite and arsenate are present in biological systems in equilibrium at any given time, then the risk factor should be adjusted to take into account the small amount of arsenite present.

According to the AWPI (36C), the EPA has found no convincing evidence in support of in vivo interconversion of arsenate to arsenite and, therefore, the Agency should acknowledge that arsenate and arsenite should be treated as separate chemicals and cease regulating on an unfounded association.

Agency response:

The scientific literature contains many studies showing that man and other mammals oxidize trivalent arsenic (arsenite) to pentavalent arsenic (arsenate) (PD 2/3). However, until recently, there was no firm evidence demonstrating the in vivo reduction of pentavalent arsenic to trivalent arsenic. Because of analytical difficulties in speciating inorganic arsenic and separating it from its methylated metabolites, the older metabolism studies of arsenic did not provide clear information about in vivo conversion of arsenic valence states (Rispin, 1983).

However, Yamauchi and Yamamura (1979) provide suggestive evidence that in vivo reduction of arsenate takes place in the human body. In this study, a human subject ingested extract of seaweed containing 86% of the arsenic as arsenate. More arsenite than arsenate was excreted in the urine. This would suggest that in vivo reduction took place in the human body. In vitro studies also support the hypothesis that pentavalent arsenic may be reduced by tissues. Incubations of arsenate with human erythrocytes (Ataullakhanov et al., 1978) and tissue homogenates (Uthe and Reinke, 1975) led to formation of trivalent arsenic (Rispin, 1983).

In a series of experiments, in mice and rabbits, Marie Vahter and Colleagues (1983) have proven definitely that arsenate is reduced to arsenite in vivo. Not only has arsenite been found in the urine and plasma of mice one hour after dosing with arsenate, but rabbits dosed at very low levels of arsenate excreted 10% of the total administered dose as arsenite in 4 hours (Rispin, June 27, 1984).

The results of these studies demonstrate the in vivo reduction of arsenate to arsenite. Accordingly, the interconversion of arsenate and arsenite is firmly established, justifying regulation of the two chemicals together (Rispin, June 27, 1984).

Comment Issue #2: The analyses of Jung, Petres and co-authors cannot be used as evidence that pentavalent arsenic is mutagenic

The AWPI (36C) states that there are no reliable data pertaining to the mutagenic potential of arsenate using mammalian systems for the following reasons: The analyses of Jung, Petres and co-authors (Jung et al., 1969; Jung and Trachsel, 1970; Petres et al., 1970; Petres and Berger, 1972; Petres et al., 1974; Petres et al., 1975) pertaining to arsenate mutagenicity and cited by the Agency in the PD 2/3 (Table II.C.1, 112-116), contain errors in methodology and conclusion (AWPI, 36C). Any in vitro mammalian assay system must have fortification with mammalian serum and the serum will reduce pentavalent arsenic to trivalent arsenic early in the test. Serum contains free cysteine; cysteine may also be added to the culture medium (AWPI, 36C). Cysteine and serum will then quickly chemically reduce the arsenic as demonstrated by Uthe et al. (1975) (AWPI, 36C).

Agency Response:

The issue of mammalian interconversion of pentavalent and trivalent arsenic has been extremely important to the development of the Agency's regulatory position on the inorganic arsenical wood preservatives. Recent studies indicate that arsenical interconversion occurs in vivo (Yamauchi and Yamamura, 1979; Vahter, 1983). Because of this metabolic interconversion of pentavalent and trivalent arsenic in mammals, the Agency believes that exposure to the two forms cannot be dealt with separately for the purpose of assessment of health effects. Arsenic in treated wood occurs primarily in the pentavalent state. The Agency has based its evaluation of the mutagenic (and teratogenic) potential of inorganic arsenic on studies involving both valence states of the chemical. Not only do the two states of arsenic have somewhat similar effects and possibly similar mechanisms, but the potential for interconversion of the two forms in vivo (see Agency Response to Comment

Issue, #1) lends credence to this position (Sochard, 1982 and 1984a).

Until new studies are presented to the Agency refuting the work of Jung et al. and others as cited by AWPI (36C) the policy of employing a worst case risk estimate compels the EPA to accept that work as providing positive evidence of pentavalent arsenical mutagenicity.

The Agency is aware that serum fortification is necessary for mammalian cell cultures, and that serum may contain free cysteine which can act as claimed by AWPI. However, since all mammalian systems contain serum in the _in vivo_ situation, and living systems are of concern, there is little reason to object to the use of serum fortification of _in vivo_ mammalian cell systems (Sochard, 1982).

Comment Issue #3: _B. Subtilis_ assay of pentavalent arsenic mutagenicity

The AWPI (36C) states that Nishioka's (1979) _B. subtilis_ mutagenicity is unacceptable because meat extract was used in the test, which would cause reduction of arsenate to arsenite. This methodology could lead to an erroneous conclusion concerning interconversion of arsenate to arsenite.

Agency Response:

The nutrient medium used by Nishioka (1975) was Difco Nutrient Broth which probably contained meat extract. If the medium is heated to temperatures above that necessary to achieve sterilization, certain pyrolysis products may be formed which are mutagenic. Indeed this medium may produce false positives; likewise, false positives would also be apparent in the experimental control. No evidence of false positives was shown by Nishioka (1975) (Sochard, 1984a).

The _B. subtilis_ assay is a standard method, and the Agency has no reason to reject the data provided until new studies are published in the literature or presented to the Agency for evaluation (Sochard, 1982 and 1984a).

Comment Issue #4: The mutagenicity of inorganic arsenic due to genotoxic (DNA alteration) effects

The AWPI (36C) states that neither valence state of arsenic (i.e., trivalent or pentavalent) is capable of causing genotoxic results and, therefore, is not mutagenic. Koppers Company, Inc. (85) also submitted a review of published literature and laboratory experiments (Simmon, 1983) which concludes that arsenical compounds may be clastogenic (cause chromosomal breakage) but that the evidence does not support the EPA's contention that arsenic is mutagenic.

Agency Response:

In its review and reevaluation of available mutagenicity studies involving both trivalent and pentavalent arsenicals, the Agency has found that available data support the position that arsenic is mutagenic.

Results of a dominant-lethal assay (University of California, 1977) submitted by the AWPI indicated a significant increase in implantation deaths of fetuses due to arsenite exposure. This increase was noted at three weeks post-treatment at which time the mating of the animals represents meiotic division. In support of these observations, the study by Benko et al. (1968) shows direct histological evidence that mouse gonadal tissue deteriorates following forced feeding (gavage) of arsenite (Sochard, 1984a).

Koppers Company (85) presented as supportive evidence for the nonmutagenicity of trivalent and pentavalent arsenic a "Review of Evidence for Mutagenicity of Inorganic Arsenical Compounds" compiled by Clement Associates, Inc., dated December 20, 1978. On page 6 of that document is the following statement: "Weighing all this (mutagenicity) evidence, we believe the most balanced interpretation to be that there is a substantial amount of indirect evidence suggesting that certain arsenic compounds, primarily trivalent arsenic, may be mutagenic; only sketchy direct evidence for mutagenicity and limited data against the hypothesis." The following is stated on page 7: "Given the evidence reviewed herein, we believe that it is fairly likely that trivalent arsenic compounds would prove to be mutagenic in *E. coli* and mammalian systems when properly tested. The evidence for the mutagenicity of *pentavalent* arsenic compounds is much more sketchy, however."

The Agency agrees with the views cited above by Clement Associates. In the Agency's view, employing the "worst case risk estimate" compels acceptance of the evidence for mutagenicity of both trivalent and pentavalent arsenicals (because they interconvert *in vivo*) until appropriate test evidence is provided refuting this interpretation (Sochard, 1984a).

Comment Issue #5: Inorganic arsenic mutagenic assay measurement of the zone of inhibition

The AWPI (36C) contends that the Nishioka (1975) study does not demonstrate a mutagenic effect for arsenate because it is virtually impossible to accurately quantitate a 1 mm difference in the assay system used. Because of the lack of sensitivity in the assay system used, it can not be concluded that pentavalent arsenic was mutagenic. Conversely, the zone of inhibition with trivalent arsenic was an order of magnitude greater.

Koppers Company, Inc. (85) also states that Simmon (1983) concluded that arsenic cannot be considered a mutagen based on microbial assays and experiments with human lymphocytes because the studies cannot be reproduced.

Agency Response:

Although it may be better to utilize a more sensitive bacterial strain which would provide a larger inhibitory zone, if an experimental result is reproducable by another laboratory, it has been validated.

Studies by Kada et al. (1980) have shown using a similar test system (*B. subtilis* rec. assay with strains H 17 and M 45) that 45 different inorganic arsenicals, including As (+3) and As (+5) species, produced positive results for mutagenicity. Until new studies are presented to EPA refuting these data, the Agency will continue to assume that both arsenate and arsenite are potential mutagens (Sochard, 1984a, and Griffin, 1983).

Comment Issue #6: In situ test for arsenic mutagenicity

The AWPI (36C) contends that Casto (1977) used an in situ technique that is obsolete and considered of limited value by today's standards.

Agency Response:

The Agency agrees with the AWPI's contention in that studies such as Casto's, which provided positive results concerning arsenite and point mutations, may have limited value. However, obsolescent test methodology does not necessarily invalidate the results of any such studies (Sochard, 1982).

Comment Issue #7: PD 2/3 references and arsenic mutagenicity

Koppers Company, Inc. (85) submitted an analysis of all PD 1 arsenic mutagenicity studies (reviewed in the PD 2/3) (Clement Associates, 1978) which concludes that none of the studies provide direct evidence of pentavalent arsenic mutagenicity. The AWPI (36C) also states that none of the references reviewed in the PD 2/3 should be used to indict arsenic as mutagenic.

Moreover, Koppers (85) states that Simmon concluded in post-hearing comments to the July 1982 OSHA Hearings on the inorganic arsenicals that arsenic cannot be considered a mutagen based on microbial assays and experiments with human lymphocytes because the studies can not be reproduced.

Agency Response:

A reevaluation of these PD 2/3 studies (Tables I-III, Sochard, 1982) indicates that there is multi-test evidence that both arsenate and arsenite interact with DNA to produce chromosomal aberrations, somatic cell DNA damage and gonadal damage, all with potential ensuing heritable effects (Sochard, 1982, and Sochard, 1984a).

In addition, the Environmental Health Committee of the Science Advisory Board of EPA has reviewed the "Health Assessment Document for Inorganic Arsenic" (U.S. EPA, June 1983) and has concurred with the Agency's statement that arsenic is to be judged as an environmental mutagen (Griffin, 1983).

The Agency is aware that metals other than arsenicals are frequently negative in microbial assays. These compounds actively produce cytogenic effects, various kinds of tumors, and other effects reflecting mutagenicity and/or genotoxicity in a spectrum of mammalian test systems.

Inorganic arsenicals have been shown to depress humoral immunity. Current evidence indicates the expression of this immune response involves activation of a gene. The demonstration of immunodepression by inorganic arsenicals plus their activity as clastogens in human lymphocytes suggests a cause and effect relationship. The immunosuppressive effect could be due to the clastogenic effect of inorganic arsenicals on the immune genes (Sochard, 1984b).

A number of positive mutagenic or otherwise genotoxic effects remain as evidence for inorganic arsenicals. These include: clastogenic effects, interference with DNA repair mechanisms, direct toxicity to mammalian gonads, depression of the humoral immune response, and positive effects in selected microbial test systems for mutagenicity (Sochard, 1984b). The Agency reiterates its position that inorganic arsenicals are mutagenic.

Comment Issue #8: Inorganic arsenic teratogenicity/fetotoxicity

Friends of the Earth (FOE) (64) state that inorganic arsenic causes birth defects. The AWPI (78) states that the Agency has failed to distinguish between the fetotoxic effects of pentavalent and trivalent inorganic arsenic. The AWPI (36C) also contends that the Agency has relied upon studies which use inappropriate routes of exposure to demonstrate teratogenic and fetotoxic effects, which may vary qualitatively or quantitatively, depending upon changes in metabolism (detoxification, elimination) associated with the different routes of administration. In addition, the AWPI (36C) presents discussions of animal fetotoxicty studies (Hood et al., 1978; Baxley et al., 1981; Hood, 1978; Hood, 1979; Hood et al., 1977), some of which indicate that maternal toxicity occurs in the same narrow dosage range as fetotoxicity, thus implying that adequate protection of the parent provides adequate protection of the fetus.

Agency Response:

The Agency has reevaluated the studies cited in the PD 2/3 (pages 130-138, Table II.C-2) and has determined that they should not be used to develop a human teratogenic/fetotoxic risk assessment because the arsenic was administered by injection, an inappropriate route of administration for humans (PD 2/3 p. 128). However, these studies are still considered to be supportive of the teratology and fetotoxic presumption.

The Agency also recognizes several deficiences in studies cited in the PD 2/3 [Hood et al. (1977), Matsumoto et al. (1974), Kimmel and Fowler (1977) and Baxley et al. (1977)] to support a provisional teratogenicity no-observed-effect level (NOEL) at 5.0 mg/kg/day for inorganic arsenite or arsenate which used oral administration, a more appropriate route of exposure for occupational risk analysis of teratogenic/fetotoxic effects. In one or more of these studies:

1) Gavage was not continued daily throughout organogenesis. Human occupational teratogenic/fetotoxic risk assessments require an animal model in which dosing is conducted at least daily throughout organogenesis, rather than for just a few days (Van Ormer, 1982c, and Sochard, 1983).

2) Maternal toxicity was not reported so that the excess risk to the fetus could be determined. It is necessary to compare the dosage

producing significant maternal toxicity to the dosage causing significant terato-fetotoxicity (Van Ormer, 1982c, and Sochard, 1983).

3) The effect level or the no-observed-effect level (NOEL) are unclear, suggesting that any observed effect is in a range which extends beyond the one or two dose levels used in the study. Generally, teratology studies using less than three dosage groups do not provide sufficient data to develop adequate dose-response curves for fetotoxicity, teratogenicity and maternal toxicity (Van Ormer, 1982c, and Sochard, 1983).

4) A NOEL was not reported for fetotoxicity in the same study with an effect level for either teratogencity or fetotoxicity (Van Ormer, 1982c, and Sochard, 1983).

Consequently, the Agency has determined that the provisional teratogenicity NOEL of 5.0 mg/kg/day for inorganic arsenite or arsenate, cited in the PD 2/3, cannot be supported with the studies currently available (Van Ormer, 1982). Deficiencies in the studies cited above cause the Agency concern that teratogenic/fetotoxic effects may be produced by oral administration of an inorganic arsenic species. Therefore, the Agency will require teratogenicity/fetotoxicity studies using Agency approved protocols to fill all data gaps pursuant to Section 3(c)(2)(B) of FIFRA.

Comment Issue #9: Sensitivity of animals and humans to arsenic toxicity

The Society of American Wood Preservers, Inc. (53), referring to the PD 2/3 (pgs. 233-240), states that "Comparisons between man and animal are for LD_{10} and LD_{50} levels, respectively. Acute toxicity comparisons of the same lethality indicate that man and animals are affected by about the same dose."

Agency Response:

The Agency agrees that the referenced data do not show a difference in sensitivity to arsenic between man and animals. However, the data presented are Lethal Dose Lowest Observed (LDLO) for man (not LD_{10}) and Lethal Dose Fifty (LD_{50}) for animals. The LDLO is an uncommon notation and is used in an attempt to indicate how small a dose can kill a person. An LDLO in man should not be compared directly with an LD_{50} in animals since the human data can represent a range of values from a true LD_1 through an LD_{100}. A human LDLO is comparable to an animal LD_1 or LD_{10}. If the human value is higher than either of these values, there is no difference between man and the test animal (Zendzian, 1982).

In the referenced PD 2/3, LD_1 or LD_{10} data are not available. In general, if the human LDLO is no lower than approximately one tenth of the animal LD_{50}, man is no more sensitive than the laboratory animal. On the basis of the data presented, there is no indication that man is more sensitive to the lethal effects of arsenic than other animals (Zendzian, 1982).

Comment Issue #10: Inorganic arsenic oncogenicity: genotoxic carcinogens (alters the DNA structure) vs. epigenetic carcinogens (prevents DNA repair once a break has occurred).

The AWPI (36C), Osmose (41) and the SAWP (53), state that while the Agency's Carcinogen Assessment Group's (CAG) risk model may accurately apply to direct (genotoxic) carcinogens, a threshold exists for indirect (epigenetic) carcinogens; that is, arsenic may be acting as a co-carcinogen, or in conjunction with other causative agents. The commenters state that the CAG's risk model does not accurately describe risks associated with indirect carcinogens and would indicate risk exists in low dosages even though none exists.

Agency Response:

The CAG has used the linear model to estimate an upper bound for risk from inhalation exposure to inorganic arsenic. The data are consistent with this model. While the "threshold" hypothesis, mentioned by the AWPI (36C) is also consistent with the data, one cannot conclude that there is no risk. There is no indication as to what is actually occurring at low doses. Therefore, the Agency has concluded that it would be prudent to adopt a conservative approach and use the linear model to estimate carcinogenic risk to humans (U.S. EPA, June, 1983, and SAB Transcript, 1983). See Section II.A for a detailed analysis of the risk model.

Comment Issue #11: Higher skin cancer rates should be found in U.S. cities with high levels of arsenic in drinking water

The AWPI (36C) contends that if the CAG dose response model (a predictor equation) (Albert, 1978) is correct, U.S. populations should have the skin cancer rates predicted through use of Taiwan drinking water data (Tseng, 1968). Morton et al., (1976), Southwich et al. (1980), Vig (to be published) and Harrington et al. (1978) found that, since selected counties or cities in Oregon, Utah, Nevada and Alaska had high arsenic levels in their drinking water and no increase in skin cancer, there must be another factor causing skin cancer in Taiwan (AWPI, 36C).

Koppers (72) submitted a study by Southwick et al. (1981) which presented epidemiological data concluding there was no significant increase in mortality associated with exposure to arsenic in drinking water in Millard, Utah.

Agency Response:

The Taiwan study (Tseng, 1968) surveyed the prevalence of skin cancer among 40,421 lifetime Taiwanese residents. The sample sizes, water concentrations and duration of exposure for the studies in each of the selected U.S. populations, cited in the above comment, are not large enough to detect the increases in skin cancer above the base level which is estimated by the CAG dose-response model (Albert, 1978). A feasibility study at the University of Pittsburgh's Center for Environmental Epidemiology (Andelman,

1983) on finding increased evidence of U.S. skin cancer by arsenic oral ingestion concluded: "From this review, it can be seen that the available information regarding the relationships between arsenic in drinking water and non-melanoma skin cancer in exposed populations in the United States is inadequate for determining whether the Taiwan experience is generalizable to this country."

The available data are not inconsistent with the Taiwan studies. The arsenic levels present in the communities studied in the United States were lower, and the duration of exposure shorter than for the Taiwan population. It is evident that if a suitable study population could be found, further study of the problem would be warranted. Such a population, besides having been exposed to high drinking water arsenic levels for a sufficiently long time, would need to be large enough for a statistically significant increase in non-melanoma skin cancer to be seen, over and above the background levels predicted from solar U.V. radiation" (Kuroda, 1983).

With regard to the CAG dose-response model, estimated increases in cancer rates are too small to be observed in epidemiology studies involving populations much smaller than that studied in the Taiwan analysis. Therefore, the observed negative results of epidemiology studies on skin cancer in individuals drinking water with moderately increased arsenic levels do not contradict the positive findings in the Taiwan studies (Kuroda, 1983).

The Southwick study was taken into account by CAG in the review of risk from oral exposure to arsenic. However, because of limitations in the protocol of the Southwick study (small cohort and low levels of arsenic contamination in the water), CAG did not use these results to change the risk estimates for oral exposure. The study was conducted on citizens of West Millard County, Utah, in which arsenic is a naturally occurring contaminant in the public drinking water supply. The concentration of arsenic was considerably smaller than that in the drinking water in Taiwan. A total of 250 people (145 exposed, 105 controls) participated in the Southwick study. Although no significant increase in mortality was associated with exposure to arsenic, the study was comprised of a cohort which was too small for meaningful statistical analysis. This study is summarized on pp. 5-69 to 5-72 in the OHEA document (U.S. EPA, 1983); however, the data were not incorporated into the development of risk.

Comment Issue #12: Absence of clinical effects expected after drinking water that contained arsenic

The AWPI (36C) states that certain clinical effects associated with arsenic exposure were not found in residents of Ester Dome, Alaska, who drank well water with a high arsenic content. Harrington et al. (1978) studied the dermatological and neurological effects of high arsenic levels in the well water upon Ester Dome residents. No evidence was found for increased prevalance of leukopenia, relative lymphocytosis or eosinophilia in any exposure group. For the high exposure group, the authors state "specifically, there was no increased prevalence of abnormalities in the skin or in the peripheral nervous system."

Agency Response:

Harrington et al. (1978) attempted to do a thorough study on the Ester Dome residents. However, the study has some significant deficiencies and there are important factors, presented by the investigators, which may be responsible for the absence of clinical findings (Kuroda, 1983).

The size of the study population (232 observations) is too small to detect increases in skin cancer or dermatological changes associated with arsenic ingestion.

The authors state: "The mean well-water arsenic concentration in Ester Dome (244 ug/liter) was less than half that seen in Chile (Irgolic, 1981, Tseshelashvili et al., 1980) or in Taiwan (Tseng, 1968), and 85 percent of Ester Dome residents had lived in the area for less than 10 years." The well-water arsenic levels appear to vary as a function of drawdown rate or seasonal water changes.

The authors noted that there was a poor correlation among biologic arsenic estimates, (hair, urine and nails) which may be a reflection of differences in the mode of arsenic excretion 1/.

The blood parameters selected for measurement (leukopenia, relative lymphocytosis or eosinophilia) are not specifically related to arsenic and are of limited value for demonstrating clinical arsenic effects (Kuroda, 1983).

The authors further speculate that the lack of positive clinical findings in the Ester Dome, Alaska, study, when compared to Taiwan and Chile, may be due to good nutrition of the Ester Dome residents, lack of additional environmental contaminants, and/or differences in exposure to sunlight (Kuroda, 1983).

Comment Issue #13: No health problems in populations with high arsenate levels in drinking water

The AWPI (36C) states that a new epidemiology study (Vig, unpublished) shows no health or skin problems in populations drinking water with high arsenate levels. The study compared the rate of chromosome aberrations, birth defects and incidence of cancer for people living in Fallon, Nevada, a city with drinking water containing 0.1 ppm to 0.5 ppm, with people living in Reno, Nevada, where the drinking water arsenic level is less than .005 ppm. The Reno control group had a slightly higher frequency of chromosome aberrations than the Fallon group. The Fallon group had no increase in sister chromatid exchange, no malformations or birth defects, and no increase in cancer (Vig, to be published).

1/ Urine arsenic levels correlate well with calculated daily doses, while arsenic concentrations in hair and nails represent a mean value over several months and may provide a better integrated measure of past exposure to arsenic (Kuroda, 1983).

Agency Response:

The study "Chromosome Studies on Human Subjects Exposed to Arsenic in Drinking Water," (Vig, unpublished) has several critical limitations which do not permit the Agency's agreement with the conclusions concerning the effects from arsenic in drinking water: (1) The sample size was too small to result in statistically valid conclusions (there were only 201 individuals in the study, 96 control and 105 exposed); (2) the exposure period to higher arsenic levels was only 5 years; and (3) the cohorts were not matched.

This study, with a small population and short arsenic exposure time, could not be expected to detect the increases in oncogenicity or birth defects. Although no increases in chromosome aberrations or sister chromatid exchanges were found, this does not negate the positive findings of skin cancer in the Taiwan study by Tseng (1968) (Kuroda, 1983).

Comment Issue #14: Taiwan drinking water contains alkaloids which cause Blackfoot disease and cancer.

The AWPI (36C) states that the drinking water from the endemic area of Taiwan is known to contain other chemical substances that may be the cause of the cancer and other diseases. The AWPI (36C) and the SAWP (53) contend that the water contains alkaloids which were tentatively identified as derivations of ergotamine tartrate, one of the alkaloids that can cause gangrene-like Blackfoot disease, that was associated with skin cancer in endemic areas. The AWPI (36C) suggests that the EPA review Kraybill and Shimkin (1964) and Fishbein (1972), which describe the carcinogenic properties of alkaloids.

Agency Response:

Although the alkaloid compounds may account for the finding of Blackfoot, a vaso-constrictive disease, there is no evidence that the alkaloids are related to carcinogenesis. A review of Kraybill and Shimkin (1964), "Carcinogenesis Related to Foods Contaminated by Processing and Fungal Metabolites" reveals nothing relevant to the types of alkaloids identified in the Taiwan drinking water. Fishbein (1972) mentioned that "Indole alkaloids such as vinblastine and vincristine from _Vinca rosea_ and from ergot, the lysergic acid derivations, lyseric acid diethylamide (LSD) and bromolysergic acid diethylamide have been shown to induce foetal malformations in hamsters." Neither one of these references, which are only secondary sources, support the contention that the alkaloids found in the Taiwan drinking water are carcinogenic (Kuroda, 1983).

Comment Issue #15: Beryllium caused the cancer found Antofagasta, Chile, which had high levels of arsenic in drinking water

The AWPI(36C) claims that the Antofagasta, Chile, water supply is reported to have a mean arsenic concentration of 0.58 ppm and to have caused peripheral vascular diseases and skin cancer. However, as the AWPI (36C) states, it is now known that the untreated water supply had 7.4 ppm of beryllium (Irgolic, 1981). The discovery of beryllium, a metal with salts that are known to cause cancer in laboratory animals and primary DNA damage, should be sufficient evidence to indicate that arsenic is not responsible for the increased cancer in the people drinking the water (AWPI, 36C).

Agency Response:

Beryllium has been shown to cause lung and bone cancer in test animals. The Agency is unaware of any evidence, however, of beryllium causing skin cancer in either man or animals. Although it is possible beryllium salts may have caused the skin cancer observed in Antofagasta, the presence of beryllium does not rule out arsenic as a causative factor (Kuroda, 1983).

Comment Issue #16: Due to exposure to many known or suspected carcinogens, arsenic cannot be indicted as the cause of lung cancer in smelter workers

The AWPI (36C) states that in the epidemiological studies listed in the PD 2/3, especially those involving smelters, indicate workers were exposed to many known or suspected lung carcinogens, including compounds of sulfur, antimony (antimony trioxide) and lead (lead acetate). It is illogical to indict arsenic as a cause of lung cancer (AWPI, 36C). Osmose (41) states that epidemiology studies cited by the Agency in the PD 2/3 indicate a statistical association but not cause-and-effect proof between arsenite exposure and cancer. If arsenite is an indirect carcinogen then the irritating effect of arsenite at high exposure is an indirect mechanism (Osmose, 41). Osmose (41) further comments that reviewers of metal carcinogenesis (Furst, 1978; Furst and Hars, 1969; Sunderman, 1978; 1979) conclude that certain metals, alone or in combination with other metals and sulfur, are potential indirect carcinogens but are not carcinogenic themselves. The SAWP (53) also comments that the arsenate in smelters, acting as a co-carcinogen, prevents repair of DNA breaks caused by SO_2, SO_3 and H_2SO_4 in the lung.

Agency Response:

The Agency believes there are numerous epidemiology studies which demonstrate that arsenic is a cause of cancer found in smelter workers. (PD 1, pp. 152-153 and PD 2/3, pp. 104, 107-109). Although the workers have been exposed to other known or suspected carcinogens, this does not exclude arsenic as the cause of cancer. Brown and Chu (to be published) evaluated smelter worker data and, by adjusting for the confounding effect of sulfur dioxide, determined that arsenic rather than SO_2 was the more probable carcinogenic contaminant (Kuroda, 1983).

Welch et al. (1982) studied the effects of exposure to arsenic, sulfur dioxide, asbestos, and smoking habits on copper smelter workers and determined that (1) a clear dose-response relationship between arsenic and respiratory cancer was demonstrated and (2) sulfur dioxide and asbestos did not appear to be as important as arsenic exposure (Kuroda, 1983).

The Agency is unaware of any studies demonstrating the carcinogenic ability of antimony trioxide but would welcome the opportunity to review them.

Comment Issue #17: Inorganic arsenic and excess respiratory cancer

Koppers Company, Inc. (72) and the AWPI (31) contend, based on numerous submissions made to the Agency, that inorganic arsenic poses no risk of excess respiratory cancer at exposures below 500 ug/m^3 (Schlesselman, 1983; Chemical Manufacturers Association Arsenic Panel, September 3, 1982; Consultants in Epidemiology and Occupational Health, September 2, 1982; Bromberg, September 1, 1982; Chemical Manufacturers Association Arsenic Panel, August 13, 1982; Consultants in Epidemiology and Occupational Health, August 13, 1982; Lamm, July 15, 1982; Consultants in Epidimiology and Occupational Health, July 30, 1982; Furst, no date; Woolson, August 13, 1982; University of California, February 18, 1978; Lederer, July 15, 1982, Marsh, July 18, 1982; Chemical Manufacturers Association Arsenic Panel, June 18, 1982; Consultants in Epidemiology and Occupational Health, June 2, 1982; Harding Barlow, May, 1982; McGraw, June 11, 1982; Koppers Co., Inc., June 17, 1982; AWPI, 1979; Gilbert et al., 1981; Higgins et al., 1983 Lederer and Fensterheim, eds., 1983).

Agency Response:

The Agency does not believe the cited studies support the commenters' contention that inorganic arsenic exposure levels below 500 ug/m^3 will not lead to excess respiratory cancer.

The Agency responded to comments on arsenic and cancer by AWPI, 1979 ("AWPI Response to EPA Position Document (PD 1) Volume 1: Discussion and Analysis of Risks and Benefits Associated with Inorganic Arsenic Used as a Wood Preservative") in the PD 2/3 (pp. 95-193). The submissions listed above, except for Gilbert et al. (1981), Higgins et al. (1982), and Lederer and Fensterheim (eds., 1983) were discussed at a series of hearings held by the Occupational Safety and Health Administration (OSHA) on July 13-16, 1982. OSHA published a thorough analysis of the information presented during and after the hearings. This analysis appeared in the Federal Register, Volume 48, pp. 1864-1903, on January 14, 1983. The Agency's Carcinogen Assessment Group (CAG) used this information, with other sources, to prepare the risk estimate section of the "Health Assessment Document for Inorganic Arsenic" U.S. EPA, June 1983 - External Review Draft (McGaughy, 1983).

Studies available after PD 2/3 publication include Gilbert et al. (1981), Higgins, et al. (1982), Entertine and Marsh (1983); Lederer and Fenitercheim, eds.); Lee-Feldstein (1983 Lederer and Fensterheim, eds.), Southwick, et al. (1983, Lederer and Fensterheim, eds.) The Agency's review of Gilbert et al. (1981) will be incorporated into the Agency's final OHEA "Health Assessment Document for Inorganic Arsenic." The protocol of this study had many limitations and will not lead to any revisions in the risk calculations.

Higgins et al. (1982), Enterline and Marsh (1983) and Lee-Feldstein (1983) are studies of Anaconda and Tacoma smelter workers. These new studies and a series of new analyses from the National Cancer Institute by Brown and Chu (1983 a, b, and c) were used by CAG to revise its 1980 risk estimates for inhalation exposure (Rispin, 1984) (see Section II.A.1).

Comment Issue #18: Lung tumors in vineyard workers are caused by copper not arsenic

The AWPI (36C) and the SAWP (53) report that Villar (1974) found tumors in vineyard workers lungs ("vineyard sprayer's lung") in Portugal, where arsenic had never been used on the vineyards. Bordeaux mixture (copper sulfate and lime) was used and Villar ascribed the "vineyard sprayer's lung" to copper.

Agency Response:

Villar's (1974) study, which analyzed 15 cases, concerned pathological changes involving granulomas that were not necessarily cancerous. There is, at best, a tenuous connection between lung cancer and inflammatory reactions in the lungs not specifically diagnosed as cancer. This study does not provide sound data to attribute vineyard sprayer's lung cancer to inhaled copper sulfate (Kuroda 1983).

Comment Issue #19: EPA did not adequately consider the AWPI's comments on the NIOSH orchard worker study

The AWPI (36C) states that there is no reasonable basis for the NIOSH and Milham (1974, 1975) conclusion that lead arsenate was the probable cause of increased lung cancer among the orchard workers. The AWPI (36C) contends that during the 20-30 years prior to the observation of increased lung cancer, at least 10 compounds were used in addition to lead arsenate and it seems likely that the combination of oils and sulfur, or DDT in combination with other pesticides, was the real cause.

The AWPI (36C) also contends that even though the workers in the Milham study (1975) were exposed to many pesticides prior to their deaths, a comparison of the predicted mortality rate (PMR) for respiratory system cancer reveals that the younger workers, least exposed to lead arsenate (usage discontinued in approximately 1948), had the excess cancer.

Agency Response:

A more recent study by Milham (1983) found an increasing trend over time of lung cancer among orchard workers. Milham reported that "The lung cancer excess seems to be increasing in that the PMR for deaths during 1950-1959 was 102; 1960-1969, PMR=121; and 1970-1979, PMR=143." Milham (1983) suggests that "The orchard workers excess is probably related to the use of arsenical-based pesticides before 1945." However, since the only agriculture-related populations, i.e., orchardists and nurserymen, exposed to arsenic developed respiratory cancer, this provides evidence that arsenic, and not combinations of oils and sulfur, or DDT and other pesticides, is the cause of cancer (Milham, 1975). Also, male workers who were occupationally exposed to arsenic pesticides during the manufacturing process had increased mortality from lung cancer (Mabuchi et al., 1980) (Kuroda, 1983).

The basis for the statement concerning younger workers developing the excess cancer is not clear (Kuroda, 1983).

Comment Issue #20: Arsenic in drinking water of animals has a strong cancer inhibiting effect

The AWPI (36C) contends that the Kerkvliet and Steppan study (1974) demonstrated that levels of arsenate in drinking water as high as 100 ppm increased the latent period and decreased the incidence of viral-induced tumors in mice caused by injection of MSB sarcoma cells.

Agency Response:

The Agency is not persuaded by the Kerkvliet and Steppan (1974) study which relates only to transplanted cancer cells and not to cancer induction; therefore, it is not relevant to the mechanism by which arsenic causes cancer. Also, the relationship of the immunotoxicologic effect of sodium arsenate in mice inoculated for 12 weeks to the carcinogenic potential of arsenic toward the induction of primary tumors in animals and humans with chronic exposure is not clear. Although decreased tumor incidence and increased latency of tumor formation occurred with arsenic treatment, tumor formation (with decreased survival afterwards) still was evident in treated animals. The authors did not report survival rates for animals which did not have tumors. A serious consideration is whether the arsenate levels which affect tumor growth (25 ppm and 100 ppm) are toxic over lifetime exposure (Kuroda, 1983).

Arsenic was effective as a tumor inhibitor with inoculation of 10^5 MSB cells but not with 10^6 MSB cells which suggests the effect is dependent on experimental conditions. Dose-related cytotoxicity was found in spleen and lymph node cells with inoculation of MSV tumor cells but not MSB cells; however, arsenic had no effect on regression of MSV tumor cells. The fact that arsenic inhibits tumor growth is not inconsistent with the fact that it induces skin and lung cancers. Many clinically used antineoplastic agents are known to be carcinogens. Moreover, conclusions from this study to lifetime exposure are extremely limited because 12 to 16 weeks is a very short time for animal arsenic exposure. Therefore, if arsenic had any inhibiting effect on cancer cells, it is of very limited scope and not found over the lifetime of the test animal (Kuroda, 1983).

Comment Issue #21: Sodium arsenite inhalation oncogenicity experiment

The AWPI (36C) cites a new arsenite inhalation oncogenicity study by Berteau et al. (1980) to support its position that "inhaled sodium arsenite is probably not a carcinogen to mice." An Ames test on mouse urine gave negative results.

Agency Response:

The Agency is not persuaded by the Berteau et al. (1980) study cited by AWPI which contends inhaled sodium arsenite is probably not carcinogenic to mice. Following daily inhalation of various doses of sodium meta arsenite, female test mice and controls were sacrificed at varying times during and after exposure. Berteau et al. examined and weighed select organs; the lung was reviewed histopathologically. The authors found no significant increases in lung tumors and concluded that inhaled sodium arsenite is probably not a mouse carcinogen. However, this study has several flaws, so that the results cannot be considered to demonstrate a noncarcinogenic response: (1) only female mice were used; (2) exposure time was too short, i.e., 46 weeks with an additional 120 days for observation, instead of 102 weeks (exposure for lifetime); (3) histopathological examination of only lung tissue; and (4) high incidence of background neoplasia in both cage mates and controls (Kuroda, 1983).

The Ames test performed is of limited value since only one tester strain, TA 1538, was used. TA 1538 is not one of the more sensitive strains and is not sensitive to base-pair substitution (Kuroda, 1983).

The absence of an animal model to demonstrate arsenic oncogenicity does not refute the positive epidemiology evidence that arsenic is a carcinogen (Kuroda, 1983).

Comment Issue #22: EPA has failed to demonstrate with reliable animal studies that arsenic is an oncogen

Osmose (41) contends that the EPA relied on inadequately controlled and documented epidemiology data, instead of confirmatory animal studies, as a basis for arsenic cancer theory. "Drinking Water and Health" (NAS, 1977) indicates that animal studies have not shown arsenic to be carcinogenic, even when administered as a maximally tolerated dose for a long period of time (Osmose, 41). The AWPI (36C) states that animal studies, used by the Agency to support the contention that arsenic is an oncogen, are invalid. The AWPI (36C) further comments that the Ivankovic et al. (1979) study concerns test animals exposed to a mixture of chemicals, one of which was calcium arsenate; and the oncogenicity study of Oswald and Goertler (1971), cited by the Agency as evidence that arsenic exposure resulted in positive tumor responses, consists of inadequate data.

Agency Response:

The Agency agrees that there are no good animal tests demonstrating that arsenic causes cancer and, consequently, the mechanism of arsenic oncogenicity is not fully understood. However, the human evidence (e.g., Brown and Chu, 1983; Tseng, 1968; Welch et al. 1982) is convincing that arsenic induces cancer (Kuroda, 1983).

The Ivankovic et al. study (1979) found lung carcinomas after intratrachial installation of a mixture of calcium arsenate, calcium oxide, and copper sulfate in rats. The EPA (PD 2/3, pp 106-107) has stated "This experiment strongly indicates that pentavalent arsenic can induce lung carcinomas, although the contribution of sulfate, copper, and calcium oxide cannot be ruled out until further experiments are carried out." That is, arsenate is the probable cause of the lung carcinomas but since other chemicals may have been responsible for or contributed to the lung tumors, this experiment does not show unequivocally that inorganic arsenic is a carcinogen in test animals (Kuroda, 1983).

Oswald and Goerthler (1971) do not provide convincing evidence that arsenic is an oncogen, however, the Agency has never claimed this study demonstrates arsenic oncogenicity (Kuroda, 1983).

Comment Issue #23: Inorganic arsenicals PD 1 testimonials

The AWPI (36C) comments that the Agency must use as supporting evidence the 216 testimonials submitted in response to the PD 1 that claimed, through firsthand knowledge, that no adverse effects were associated with exposure to arsenically treated wood.

Agency Response:

Reports based on first-hand experience involve limited numbers of people and can involve many uncontrolled variables which only standardized testing can control or monitor. Therefore, the Agency cannot use these submissions as evidence due to the nontechnical nature of such claims.

Comment Issue #24: Dermal absorption of inorganic arsenicals

The AWPI (36C) states that the Agency has not distinguished between insoluble arsenic per se and fixated arsenic on treated wood. The AWPI (36C) states that the Agency has not properly interpreted the reason the Occupational Safety and Health Administration (OSHA) decided not to regulate arsenical-treated wood under the OSHA workplace standard (1978); and further cites OSHA as stating that the Budy-Rashad study of Haiwaiian carpenter exposure to pentavalent arsenic wood complex cannot be considered equivalent to unbound pentavalent arsenic (43 FR 19599; May 5, 1978).

The AWPI (36C) contends that the studies of Hood (unpublished, 1979), supported by Dutkiewicz (1977), Peoples (unpublished, 1979) and Osmose (unpublished, 1980) show that dermal absorption from handling arsenical treated wood is negligible because of the highly insoluble characteristics of the surface residue. Also, the soluble arsenic content of CCA-treated wood residues is consistently low. AWPI (36C) further comments that in 1979 the ACA mixing technology was improved and resulted in increased surface cleanliness of treated wood. The AWPI submits that dermal absorption from exposure to ACA- or CCA- (oxide) treated wood should be .0000045 mg/ft^2 (.0001% total residue absorption x 4.5 mg/ft^2 Agency established surface residue level for CCA-treated wood).

The AWPI (36C) also comments that although the Agency has revised the short duration liquid dermal exposure estimate to 6 ml, it has overlooked human exposure data (Fahlstrom, 1979; University of Hawaii at Monoa, 1977; Tabershaw, 1978a, 1978b) which reduce the dermal absorption rate to 0.05% in short-term duration, an insignificant dermal exposure in actual plant operations.

Agency Response:

Inorganic salts of arsenic, no matter what their physical properties, cannot be expected to penetrate the skin. These compounds vary considerably in water solubility but lack the solubility in organic solvents that is associated with the ability to penetrate the skin (Zendzian, 1982).

Although the Peoples (1979) arsenic dermal absorption study used only two test animals (dogs), no evidence of arsenic absorption was seen in either animal. Daily excretion of arsenic was on the order of 25 micrograms, all as dimethylarsenate (DMA). These negative results are expected. Based on the properties of arsenic in the preservative form, one would not expect dermal absorption from arsenic treated wood to occur (Zendzian, 1982).

The Agency agrees that dermal absorption of arsenic from dry arsenic treated wood or from arsenic-laden sawdust is estimated to be "negligible" (Day, 1983). The exposure estimates presented in this document reflect the aforementioned revised exposure assumption for CCA and ACA treated wood and are detailed in Section II.B.1 of this PD 4.

The dermal absorbtion of inorganic arsenicals from liquid formulations was discussed in Section II.B.1 of this PD 4 and was assumed to be 0.1% (Rispin, April 18, 1984).

Comment Issue #25: Industrial plant workers background exposure to inorganic arsenicals

The AWPI (36C) states that the Agency's estimated background exposure level for inorganic arsenicals in industrial plants (.07 mg/m^3) was assessed using an outdated ACA mixing method. They point out that the EPA based estimates of CCA oxides, CCA salts and ACA on a study by the California Department of Health Services (1979), which apply only to ACA (AWPI, 36C), and that they submitted data (Employees Insurance of Wausau, 1978; Hewitt, Coleman and Associates, Inc., 1980; Koppers Co., Inc., 1978 and no date; Osmose Co., 1978; Stewart Todd Associates, 1979; Stewart Todd Associates, 1980) indicating that the treating plants utilizing liquid or paste CCA concentrates are within the OSHA airborne iorganic arsenic standards. Based on these data, the AWPI claims that the CCA background level should be revised to less than 0.005 mg/m^3 (AWPI, 36C). Moreover, they believe the monitoring data presented by Stewart-Todd Associates (1980a; 1980b) supports revision of the ACA background level to less than 0.006 mg/m^3.

The AWPI (36C) also comments that more recent data (NIOSH, 1981) indicate 0.001 mg/m^3 represents background inorganic arsenic exposure levels in industrial treatment plants.

Agency Response:

The EPA's estimate of 0.07 mg/m^3 represents the upper limit of a time weighted average (TWA) found by the California Department of Health Services (1979) in an ACA plant. However, this plant may have been atypical in that the mixing systems were open and involved the mixing of dry ingredients. As discussed in Section II.B.1 of this document, the Agency has reevaluated data summarized in the PD 1 on arsenic air levels and has also reevaluated data submitted by AWPI in response to the PD 2/3 (36C, Exhibit 1 Vol. 1, pp. 244-246) showing a correlation between urine levels in humans exposed to airborne arsenic, which indicates that the level of 10 ug/m^3 is a reasonable estimate for airborne arsenic in a wood treatment plant. Therefore, the exposure estimates in this document were based on 10 ug/m^3 arsenic averaged over an 8-hour workday. This is consistent with the OSHA TLV.

Comment Issue #26: Wood foundations

The AWPI (36C) contends that, based on recently-developed data on CCA-treated wood leaching (Osmose, 1981), the Agency's revised exposure estimate for a person cleaning a flooded all-weather wood fundation (AWWF) basement (Osmose, 1981) is still too high (43.2 mg/ft^2). In addition to these leach test results, consideration of the ratio of edge grain to end grain wood (i.e., most leaching should occur at edge grain), increase in osmostic pressure in a flooded basement, as well as the fact that homeowners usually pump contaminated water out of a basement (AWPI, 1981), would yield an estimated leaching rate of 6.5 mg/ft^2.

The AWPI (36C) suggests that the Agency lower its exposure estimates for sweeping basement floors from 1,267 ppm to 354 ppm, because there are two types of dust which would collect in a basement: (1) that already on the surface of treated wood and (2) dust which accumulates over time. Also, a study used by the Agency to establish dust exposure levels in wood foundation homes (Sleater and Berger, 1977) states that "The samples taken from wood surfaces were likely to contain wood particles." Therefore, the AWPI (36C) contends that EPA's model based on sweeping basement floors, does not apply to the high value of 1,267 ppm and that the Agency must use the next lowest exposure level, 354 ppm, listed by Sleater and Berger (1977).

Agency Response:

The Agency will accept the commenter's recommendation of a leaching rate of 6.5 mg/ft^2 for flooded basements, based on the experimental evidence presented (Day, 1982). This rate was used in developing the arsenic risk (Rispin, April, 1984).

Secondly, the Agency reiterates the PD2/3 (p. 188) position that the Sleater and Berger (1977) study reported levels of 2-1267 ppm of arsenic in house dust. The higher levels were in homes where the treated wood was exposed. These data were based on analytical reports for eleven dust samples. Therefore, the Agency has determined that the highest value reported is an accurate measure of arsenic in household dust.

Comment Issue #27: Inorganic arsenicals inhalation exposure from handling and sawing wood

The AWPI (36C) states that in revising the PD 2/3 inhalation exposure estimate for handling and sawing wood, the EPA ignored monitoring data of workers handling and sawing treated wood in occupational settings. Based on data (Minnesota State OSHA, 1974 and Wisconsin Department of Human and Social

Services, 1977) submitted, the AWPI (36C) contends that 0.024 mg/m^3 rather than 0.36 mg/m^3 is a more accurate reflection of workplace airborne arsenic exposure during sawing and handling treated wood.

The AWPI (36C) also contends that for a handling and sawing wood risk assessment the Agency must also take into account that: 1) 70% of respirable dusts are retained in the lung (Thomson and Pavia, 1974), 2) an estimated less than 20% of non-respirable sawdust particles reach the bronchi, and 3) arsenic in treated wood is not the same as arsenic *per se*.

Agency Response:

Based on the data provided by the AWPI (36C) (Minnesota State OSHA, 1974 and Wisconsin Department of Human and Social Services, 1977), the Agency will assume that persons working with arsenic treated wood (sawing, nailing, fabricating) are exposed to an arsenic air concentration of 0.024 mg/m^3 (Day, 1982).

The Agency assumes there is little or no arsenic absorption in the lungs *per se* from dust or sawdust from arsenic treated wood. Most material would be deposited in the bronchial passageways, brought up by ciliary action and swallowed. Absorption would then follow from the digestive tract (Zendzian, 1982).

Conversely, Peoples and Parker (1979) have shown that significant quantities of arsenic can be absorbed from ingested sawdust. The actual portion of ingested arsenic absorbed is affected by the solubility of the arsenic compounds and the size of the particles. It is estimated that 27% and 65% of the arsenic form CCA-treated and ACA-treated wood particles that are inhaled from handling and sawing such wood are absorbed (Zendzian, 1982).

B. Comments on Benefits

The Agency received several comments on the financial impact on the home and farm market of restricted use pesticide classification from the Gibson-Homans Company (3), Coopers Creek Chemical Corporation (4), National Solvent Corporation (6), Soult Wholesale Company (8), Cedar Fence Distributors Company Inc. (9), Dries Building Supply Company (11), Sampson Paint Manufacturing Co., Inc. (12) Standard Concrete Products Company (13), Lloyd H. Daub, Inc. (15), Harboro Lumber Fuel Company (16), C. A. Niece Company (19), GAF Supply Center (21), RABCO Products (22), Michlin Chemical Corporation (25A), Missouri Department of Agriculture (28) and Carson's Hardware (29).

(39) Seven comments addressed additional costs to the consumer due to wood preservative unavailability. Sentinel Wood Treating, Inc. (2); Illinois Power Company (5) and Consumers Power Company (31) submitted comments pertaining to renewable resource waste. Cedar Fence Distributors (9), Philadephia Reserve Supply Company (17), Missouri Department of Agriculture (28), N.Y. Power Pool (30), Niagara Mohawk Power Corporation (42), Missouri Forest Products Association.

Five commenters (41) made statements concerning utility and railroad company hardship which would occur if the wood preservatives were unavailable. Illinois Power Company (5), the Association of American Railroads (34), Edison Electric Institute (35), Detroit Edison (40) and Osmose (41).

Sentinel Wood Treating, Inc. (2), National Woodworks, Inc. (24), Missouri Department of Agriculture (28), the Association of American Railroads (34), Missouri Forest Products Association (39) and the Nebraska Cooperative Extension Service (51) submitted comments concerning the effects of wood preservative cancellation on the wood industry. Good-Life, Inc. (58) commented on pentachlorophenol soil treatment.

Agency Response:

The Agency acknowledges the numerous benefits associated with wood preservatives. The comments provided no additional information which substantially changed the Agency's assessment of benefits. See Section II.C for a summary of benefits associated with wood preservative usage. Although select market segments will incur additional costs due to regulatory decisions, the Agency's risk/benefit assessment indicates that the health hazards associated with some aspects of usage are considered sufficient to warrant the required protection outlined in this document. The three wood preservatives will continue to be available for both commercial and home farm use by certified applicators.

C. Comments on Regulatory Options

Comment Issue #1: Disposal of treated wood

Illinois Power Company (5), Association of American Railroads (34), Edison Electric Institute (35) and Iowa-Illinois Gas and Electric Company (50) consider the regulation of treated wood disposal a waste of recyclable resources.

Portland Cement Association (66) reported a poisoning incident which occurred from burning treated wood. The American Wood Preservers Institute (AWPI) (36F), the National Forest Products Assocciation (NFPA) (36F) and the Association of American Railroads (71) contend that there is no evidence burning creosote-treated ties creates a health risk or pollution problem. The Department of the Army (1) states that a nonhazardous landfill should be an acceptable disposal site for treated wood.

The AWPI (36F) and the NFPA (36F) contend that the issue of treated wood disposal is related to the Toxic Substances Control Act (TSCA) and recommend burial as the most appropriate disposal measure although the EPA has no evidence that arsine gas is generated from burning arsenic-treated wood.

Agency Response:

The Agency is concerned that people will burn treated wood in fireplaces, wood-burning stoves, and the like, and be subject to adverse health effects. Jansson and Sundstrom (1978) and Rappe and Markland (1978) show polychlorinated dibenzo-p-dioxins (including HxCDD) are formed from burning or heating chlorophenates and from burning pentachlorophenol treated wood. When creosote-treated wood is burned, various oncogenic or mutagenic compounds may be formed. Wood treated with the inorganic arsenical compounds can produce toxic, arsenic containing combustion products such as arsenic trioxide ash, which is a teratogen, mutagen and oncogen, (PD 2/3, page 701). Therefore, treated wood should not be burned in open fires or fireplaces, thereby eliminating the potential for exposure to the toxic combustion products that results from burning treated wood. Treated wood may be disposed of in the ordinary trash or in accordance with the Consumer Information Sheet (CIS) guidelines detailed in Section VII.A.3 of this document. Large quantities of treated wood may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

Industry will be required to provide disposal guidelines to users of treated wood through a mandatory Consumer Awareness Program. If this program is ineffective, the Agency will promulgate a rule under TSCA to provide labeling instructing users of treated wood in proper handling and disposal precautions. For a detailed explanation of this issue see Section VII.C.

Comment Issue #2: Applicators must wear impervious gloves in all situations where dermal contact with wood preservatives is possible.

The Nebraska Cooperative Extension Service (51) and the International Woodworkers of America (IWA) (68) agree that protective clothing is necessary although the IWA offers rewording suggestions concerning potential exposure. The Illinois Power Company (5), the Association of American Railroads (34), Edison Electric Institute (35), Detroit Edison (40), Iowa-Illinois Gas and Electric Company (50), the U.S. Department of Energy (44) and Sentinel Wood Treating, Inc. (2) express concern that the recommended materials confine a lineman's movements with and on poles (35, 40, 50), are too hot (2), can crack in cold weather (35), are of questionable efficacy (44, 68) and can lead to serious electrical injury if breakthrough occurs (5).

Osmose (41) states that the applicators already wear rubber gloves. The AWPI (36F) and the NFPA (36F)recommend gloves where significant dermal contact is expected for selected uses[1]. Osmose further comments that spray applicators of creosote and pentachlorophenol for industrial and home/farm use should also wear head covering and eye protection, if required to wear a respirator and protective clothing.

The AWPI (36C) suggests a clarified option for inorganic arsenicals which would apply to liquid as well as freshly-treated wood. For brush-on application of inorganic arsenicals, the AWPI suggests revising the PD 2/3 proposal to read "impervious gloves which will reduce exposure."

The National Woodworks, Inc. (24) questions the glove requirement for handling dried pentachlorophenol-treated wood. The AWPI (36C) states that the glove requirement should not pertain to handling arsenic-treated wood because Peoples (1979) and Hood (1979) have demonstrated that there is no skin absorption of arsenic from dried CCA-treated wood because the arsenicals are fixed in the wood and surface deposits are insoluble. (See Section V. A.3.; Comment Issue #24).

Agency Response:

The Agency has not estimated a creosote dermal exposure/risk due to the variation in chemical composition of creosote. However, the oncogenic and mutagenic potential of creosote (see Section V.A.1, Comment Issues 1-12) is a sufficient basis for requiring protective clothing.

For pentachlorophenol, the revised exposure/risk estimates (see Section VI and Appendix B) justify the requirement for protective gloves and clothing. Based on the Peoples (1979) data submitted by the AWPI (36C), the Agency has determined that end-users need not wear gloves to handle dry, inorganic arsenic-treated wood since dermal absorption is neligible (Zendzian, 1982).

However, the Agency has considered the comments received pertaining to the proposed glove requirement language and has revised the proposed label language on gloves presented in the PD 2/3. The PD 2/3 proposed labeling required gloves "where dermal contact with creosote, pentachlorophenol and inorganic arsenicals is possible." The proposal has been modified to require gloves "where dermal contact is expected." For exact wording for the various use situations, see Sections VI.C (pressure treatment uses), VI.D (poles-groundline), VI.E (home and farm), VI.F (brush-on treatments for inorganic arsenicals), VI.G (sodium pentachlorophenate), VI.H (millwork and plywood and particleboard), and VII.A (end-use). The Agency has concluded that in order for the benefits of use to outweigh the risks, protective gloves impervious to the preservative being used must be worn in the specified use situations. This label modification should eliminate any requirement to wear such protective clothing where it is not necessary.

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[1] Pentachlorophenol pressure treatment; pentachlorophenol/creosote poles-groundline; industrial, home and farm use of creosote/pentachlorophenol;use of sodium pentachlorophenate; millwork, plywood and particleboard spray.

Examples of glove materials required by the Agency for each chemical will be identified on the pesticide label (see Section VI.C.2). However, it should be noted that the use of rubber gloves (listed in the comment) is not considered acceptable except for waterborne pentachlorophenol, based on data received since the PD 2/3 was published (AWPI, June 7, 1983 and Silkowski, 1982). The Agency's recommendation of protective materials for pentachlorophenol is based on Silkowski (1982) who studied "breakthrough" times (the time it takes a chemical to go through a barrier of protective material such as polyvinylchloride) for various glove materials. Because the Agency has no data on the degree of protection afforded by certain materials for creosote or arsenic formulations, the Agency will request such data in a Notice to the Registrants pursuant to FIFRA Section 3(c)(2)(B), in the meantime the Agency will require applicators to use gloves made from materials recommended by AWPI (June 7, 1983).

Comment Issue #3: Comments on Protective Clothing.

The Nebraska Cooperative Extension Service (51) agreed with the Agency's protective clothing recommendations for the three wood preservatives. The International Woodworkers of America (68) also agreed with the Agency's protective clothing proposals for creosote and pentachlorophenol usage. The AWPI (36B) and the NFPA (36B) recommended protective clothing for applicators entering pressure-treatment cylinders, those applying pentachlorophenol as a groundline treatment for poles, applying pentachlorophenol to millwork, plywood and particleboard, applying sodium pentachlorophenate when "hazard exists" and when applying 1% or greater sodium pentachlorophenate.

The Association of American Railroads (71) contends that adequate protection against creosote and pentachlorophenol applicator exposure is already provided for railroad workers due to railmounted spray rigs. The AWPI (36C) contends that protective clothing, such as disposable coveralls, is not necessary for brush-on application of inorganic arsenicals.

Sentinel Wood Treating, Inc. (2) expressed concern that the recommended protective clothing will lead to heat prostration. Monona Glove Clinic (27), the Association of American Railroads (34), Edison Electric Institute (35), Detroit Edison (40) and Osmose (41) also express this concern regarding protective clothing for pentachlorophenol and creosote usage. Edison Electric Institute (35) and Iowa-Illinois Gas (50) suggest cotton clothing for protection against exposure to creosote and pentachlorophenol during groundline treatment of poles.

National Woodworks, Inc. (24) questions the need for protective coveralls when handling dry, pentachlorophenol-treated wood. The AWPI (36C) contends that the Agency has provided no evidence that this requirement is necessary for dry, arsenic-treated wood.

Osmose (41) and Edison Electric Institute (35) also contend that the recommended protective clothing is not quantitatively justified for protection against creosote and pentachlorophenol during groundline treatment of poles and for sawing wood. Detroit Edison (40) and Osmose (41) state that regulation will increase creosote and pentachlorophenol poles groundline treatment cost; Detroit Edison (40) estimates that changing clothes will consume 25% of each workday, or amount to $25 million (1982 dollars assumed).

Agency Response:

Most of the comments are in agreement with the Agency's proposed protective clothing requirements. Those which did not agree on specific points are discussed below.

As stated previously, in the Agency response to Comment Issue #16 on creosote (Section V.A.1) and Comment Issue #9 on pentachlorophenol (Section V. A.2) the Agency agrees that, with remote control application equipment for non-pressure treatment of railroad ties, exposure would be lower than with other application methods, such as spray or brush-on. However, the applicator may also be involved in loading, maintaining and cleaning the equipment as well as mixing and/or diluting the preservatives, which provides an opportunity for exposure. Therefore, protective clothing will be required for workers applying wood preservatives to railroad ties.

Due to exposure which could result from brush-on treatment with inorganic arsenicals (Section VI.F), the Agency has concluded that impermeable coveralls are necessary for this use.

Because the specified protective clothing must be worn only at certain times (i.e., relatively short periods of time, such as entering pressure treatment cylinders, during actual non-pressure treatment application or handling freshly-treated wood), heat stress should not be a major problem. Cotton coveralls, however, do not provide adequate protection against exposure to creosote and pentachlorophenol. See Section VI.C.2 for further discussion of the types of materials which minimize dermal exposure to wood preservatives.

The Agency has reconsidered its proposal concerning the use of protective coveralls while handling dry, arsenical treated wood and concluded, based on review of potential dermal exposure data that protective overalls are not needed. Gloves will be required for handling creosote and pentachloropenol-treated wood. (See Section VII.A.1.)

Creosote for poles-groundline treatment poses potential oncogenic and mutagenic risks to humans, and pentachlorophenol poses potential oncogenic and teratogenic/fetotoxic risks, though these risks have not been quantified. Dermal exposure to poles-groundline applicators occurs during handling and applying the wet wood preservative paste. Potential splattering of solutions onto exposed skin surfaces warrants protective coveralls when using creosote and pentachlorophenol formulations.

Any increase in industrial treatment costs due to clothing modifications would be relatively minor. That is, neoprene-coated cotton overalls cost an estimated $10.50 - $18.50 per pair; a jacket costs $10.50 - $20.35. It is estimated that if this protective clothing were replaced annually, total cost to industry would equal an estimated $28,055 (Esworthy, 1980). Because wearing protective clothing in the area of the cylinder is already required by many plant safety rules (AWPI, 1980), the Agency believes that implementation costs should have little economic impact on the wood preservative industry.

Although dermal and inhalation exposures for sawing creosote or pentachlorophenol-treated wood have not been quantified, the Agency maintains that there is a potential risk associated with such activity. The oncogenic risk of sawing arsenic-treated wood has been quantified (see Section VII.A.2). The potential risks involved with sawing creosote and pentachlorophenol treated wood warrants requiring coveralls for this activity. The requirement of a dust mask when sawing treated wood is also necessary.

Comment Issue #4: Protective clothing disposal

In lieu of the Agency's PD 2/3 proposal to dispose of contaminated protective clothing in accordance with the instructions for pesticide container disposal, the Association of American Railroads (34) suggested general trash disposal as an adequate method of discarding contaminated protective clothing. Osmose (41), the AWPI (36B and 36C) and the NFPA (36B) contend that this proposal is duplicative of existing regulations (e.g., RCRA).

Osmose (41) requested specification of disposable clothing.

Agency Response:

The intent of the Agency's position on disposal of contaminated protective clothing is to prevent continued usage of obviously contaminated clothing, and to provide for safe disposal of the materials. Disposable clothing would include relatively inexpensive, lightweight materials which are impervious to penetration by the pesticides.

The Agency has concluded that protective clothing should be changed when it shows signs of contamination, that it should be left at the treatment plant at the end of the workday, and that worn-out protective clothing or disposable clothing should be disposed of in a general landfill, in the trash, or any other manner approved for pesticide disposal. Protective clothing that has been contaminated with inorganic arsenicals must be disposed of in a manner approved for pesticide disposal and in accordance with State and Federal regulations. See Section VI.C.6 of this document for additional details. This is consistent with existing regulations for disposal of unused pesticide formulations [subtitle C of RCRA (Resource Conservation and Recovery Act)].

Comment Issue #5: Leaving protective clothing at treatment plant and cleaning of protective clothing

The AWPI (36C) agreed with the PD 2/3 recommendation that protective clothing/equipment should be left at the plant. The International Woodworkers of America (68) questioned whether wearing contaminated clothing on successive days will be discouraged, whether cleaning of protective clothing will be required, as well as specific details (replacement and frequency of cleaning) of this requirement.

Agency Response:

The Agency has concluded that, in industrial settings, protective clothing should be left at the plant at the end of the day to avoid potential household contamination and that protective clothing should be changed when it shows obvious signs of contamination (Section VI). For home and farm uses, poles-groundline, and brush-on treatments of the inorganic arsenicals, the Agency has concluded that protective clothing should be changed when contaminated with the pesticides, non-disposable protective clothing should be laundered seperately from other household clothing, and disposable or worn-out protective clothing should be disposed of in a general landfill, in the trash, or any other manner approved for pesticide disposal. Inorganic arsenically contaminated protective clothing must be disposed of in a manner approved for pesticide disposal and in accordance with State and Federal regulations.

The Agency will not address the specific details regarding replacement or frequency of cleaning protective clothing; these are issues that should be resolved by the industry/union negotation process.

Comment Issue #6: Respiratory protective equipment

Sentinel Wood Treating Company (2), Kerr-McGee Corporation (33), the Association of American Railroads (34) and Edison Electric Institute (35) commented on the PD 2/3 proposals for the use of a respirator for various exposure scenarios for the three wood preservatives. Comments refer to worker discomfort, lack of quantifiable pentachlorophenol and creosote air concentrations as a basis for the requirement, unnecessary Agency exposure limits due to existing OSHA standards, workers affected and reliance on manager's discretion. The U.S. Department of Energy (44), also commenting on PD 2/3 stipulations, states that a respirator should be NIOSH-approved.

The AWPI (36B) and the NFPA (36B) stated that either the concept of a "threshold limit value" (TLV), which would trigger the respirator requirement, or OSHA's Permissible Exposure Level (PEL), which sets the maximum air concentration over an 8-hour period at 0.5 mg/m^3 should be adopted for pentachlorophenol/sodium pentachlorophenate for opening and/or entering millwork/plywood pentachlorophenol vats, pressure treatment and spray cylinders, and for cleaning sapstain control tanks.

The AWPI (36C) also stated, with regard to the PD 2/3 inorganic arenical proposed regulatory options, that inhalation exposure in or around a cylinder is no greater than background air arsenic dust levels in treatment plants, which does not justify requiring use of a respirator, and therefore a respirator should not be required in cylinders. AWPI (36) also state that if a respirator is required, the Agency should specify the type.

The AWPI (78), commented that proper respirator use and fitting should be covered by state training programs for restricted-use applicators. AWPI (36C) contends the dust mask requirement for working outdoors in arsenic wood-treating plants should be dropped since revised exposure data (see Comment Issue #22) indicates background and most personal monitoring levels are less than OSHA requirements (AWPI, 36C). However, the International Wood Workers of America (IWA) (68) and Friends of the Earth (FOE) (64) are concerned that a dust mask requirement for treatment plant applicators, proposed at the wood preservatives April 14, 1983, public meeting[1], would not provide sufficient protection for arsenic pressure treatment plant applicators. The IWA (68) also questions whether required air samplings refer to personal or area samples.

The AWPI (78) comments that pentavalent arsenic is not associated with excess respiratory cancer risk, at less than 500 ug/m^3 (Higgins, 1983), and therefore, the dust mask requirement proposed in the PD 2/3 and April 14, 1983, public meeting is not necessary.

Illinois Power Company (5), the Association of American Railroads (34) and Edison Electric Institute (35) object to the dust mask restriction for sawing and fabricating pesticide-treated wood and request clarification of "fabrication" with wood. The AWPI (36C) agrees with the dust mask requirement for sawing treated wood only because general sawdust exposure presents a health hazard.

Agency Response:

Based on the PD 2/3 qualitative estimates of creosote risks, revised pentachlorophenol and sodium pentachlorophenate air concentrations and dermal absorptions (see Section II), the Agency has concluded that MSHA/NIOSH-approved respirators are required for those pentachlorophenol and creosote uses which include opening and entering pressure treatment cylinders. Based on qualitative and quantitative data, respirators will also be required if a visible mist (aerosolized solution) is present in the vicinity of an enclosed spray booth during non-pressure uses of pentachlorophenol and sodium pentachlorophenate. The requirement of a respirator is necessary for the benefits of use to outweigh the risks in these exposure situations.

The Agency has reevaluated the regulation proposed in the PD 2/3 which would require that all arsenic treatment plant workers wear dust masks. In view of new data and a revised risk assessment (see Section II of this PD-4) the Agency has chosen a permissible exposure limit (PEL) of 10 ug/m^3 averaged over eight hours for airborne arsenic. Employees in the work area of an arsenical-wood treatment plant must wear properly fitting, well maintained, high efficiency MSHA/NIOSH-approved filter respirators if the level of inorganic arsenic in the plant is unknown or exceeds the 10 ug/m^3 PEL. For a more detailed discussion of this issue see Section VI.C.1.

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[1] The Agency held a public meeting on April 14, 1983 (See 48 FR 13257, March 30, 1983 for announcement of meeting) to give interested persons the opportunity to comment on certain changes to the decision proposed in the Preliminary Notice of Determination (46 FR 13024-13029, February 19, 1981) as set forth in the Position Document 2/3. The comments received have been considered in the development of this final decision and are discussed in detail in this Position Document (PD 4). The final position set forth herein reflects changes made in response to such comments and further evaluation by the Agency since receipt of the comments.

Fabrication can be defined as construction or manufacture with treated wood (e.g., machining or nailing), which would include activities which may lead to user inhalation exposure to airborne treated wood particles and which can be prevented by using a dust mask. The Agency is recommending the use of dust masks for all treated wood end-users who will be exposed to airborne treated-wood particles, regardless of the actual occupation (e.g., utility, railroad workers, home and farm) of such users. A more detailed discussion of the basis for this requirement is contained in Section VII.A.2.

Comment Issue #7: Prohibition of treated wood use to prevent direct exposure to domestic animals, livestock, as well as contamination of food, feed, drinking and irrigation water

Illinois Power Company (5), the Missouri Department of Agriculture (28), Consumers Power Company (31), the Association of American Railroads (34), Edison Electric Institute (35), the Missouri Forest Products Association (39) and Iowa-Illinois Gas and Electric Company (50) commented that the wording of this PD 2/3 proposed prohibition, if strictly interpreted, would eliminate all agricultural uses of pentachlorophenol (28), utility poles support structures (31) and treated wood bridges (34). Edison Electric Institute (35), stating that exposure does not constitute contamination, suggested a prohibition against continuous exposure. The Missouri Department of Agriculture (28) and the Missouri Forest Products Association (39) cite a study (Van Gelder, 1977) which concludes that inadvertent exposure of cattle to pentachlorophenol-treated wood could not result in adverse health effects to humans. According to the Illinois Power Company (5), the relatively short life span of an animal would prohibit any measurable milk and meat preservative level increase, while the Missouri Forest Products Association (39) contends that contamination of animals would be controlled through threshold limit values (TLV's) for feed and water.

The AWPI (36B) and the NFPA (36B) cite several studies (Firestone et al., 1979; McConnell et al., 1980; Forsell et al., 1980; Kinzhill et al., 1980; Osweiler, 1980; (unpublished); Van Gelder and Greichers et al., 1979) which indicate that, at the actual levels of exposure within a barn containing pentachlorophenol, no adverse health effects are expected with the exception of pig farrowing houses and poultry bedding, for which a voluntary information program can warn users of the hazards. These commenters contend that wood treaters cannot be required to know the end-use of their wood.

The AWPI (36B) states that the Agency should clarify whether concern with domestic animals is due to food contamination or animals' health. The Missouri Forest Products Association (39) and the AWPI (36C) state that use of treated agricultural stakes show no additional dietary contamination (Levi et al., 1974; Jelinek and Cornelinsen, 1977; and Yoder, 1981) and that prohibition of use of stakes would also be very costly. The AWPI (36C) maintains that brush-on inorganic arsenicals should be allowed on these stakes because the Agency and the FDA have already determined that low level organic arsenical food residues are acceptable.

Agency Response:

The intent of the Agency's proposed restriction concerning treated wood and domestic animals is to prohibit domestic animals from continued treated wood exposure. The principal problem regarding animal contact with treated wood is potential chemical residues in food products of animal origin rather than toxicity in animals. For example, the relatively short life span of a food animal does not preclude measurable amounts of pentachlorophenol in milk and meat (Firestone et al., 1979).

According to the 1971 Environmental Protection Agency/Food and Drug Administration memorandum of understanding regarding matters of mutual responsibility under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the EPA has the responsibility for food additive regulations for pesticides that are added to food contact materials to protect the food from pests. All other petitions for the use of pesticides in food contact materials are assigned to FDA. Wood preservatives, therefore, are subject to regulation by FDA if the wood is used as a food contact material. Specifically, preserved wood cannot be used where the preservative may become a component of food or feed unless such use has been shown to be safe and a food additive regulation promulgated under section 409 of the FFDCA (Hile, 1983). However, registration and labeling of the preservatives themselves which may be required by FIFRA are under EPA's jurisdiction (Hile, 1983).

FDA has issued a regulation (21 CFR 178.3800) for the use of pentachlorophenol and sodium pentachlorophenate at levels up to 50 parts per million in wood contacting raw agricultural products. Creosote and inorganic arsenicals are not currently authorized for uses where they come in contact with raw agricultural products (Hile, 1983). FDA has also not issued any regulations for wood preservatives in treated wood which may come in contact with food or feed. Therefore, the Agency is requiring that the consumer information sheet (CIS) contain a statement prohibiting treated wood coming in contact with food and feed. If registrants wish to provide for use of treated wood in contact with food and feed, FDA must be petitioned to obtain approval for that use.

EPA has established human drinking water restrictions and has recommended discontinuation of use of coal tar-based and associated materials, which may result in drinking water contact (Cotruvo, 1983). Accordingly, the Agency will require either through the CIS or, if that proves to be ineffective, under TSCA that creosote-treated wood should not be used where it will come in contact with drinking water. Based on health-related criteria established by the National Academy of Sciences (NAS) Committee on Waste Treatment Chemicals (1983), the EPA will also require through the CIS or under TSCA that neither pentachlorophenol-treated or arsenic-treated wood be used where it may come into contact with public drinking water (Cotruvo, 1983). Use of treated wood for docks and bridges where there may only be incidental contact with drinking water will not be prohibited. Lastly, the EPA will also require through the CIS that pentachlorophenol-treated and creosote-treated wood not be used where it may come into contact with drinking water for domestic animals. Arsenic-treated wood will be allowed for such uses, however, because the arsenic levels in water which is in contact with treated wood are below 200 ppb, a level stated to be acceptable (U.S. EPA, March 1973).

Comment Issue #8: The prohibition of applying creosote, pentachlorophenol and inorganic arsenicals to wood intended for indoor use

Several commenters contend that the benefits of indoor use of treated wood justify continued use and proposed alternative means of reducing exposure. The American Institute of Timber Construction (10) and Structural Wood Systems (14) request that interior use of pentachlorophenol-treated and inorganic arsenical-treated wood be permitted for glued laminated timber structural members because current technology does not provide other preservatives that are protective, gluable and accept finish. The AWPI (36B) and the NFPA (36B) support interior use of wood preservatives by stating that pentachlorophenol is essential for pre-treatment of wood in laminated beams because it is the only pesticide for wood pressure treatment that allows proper glue bond strength.

Levin (60) commented that occupants of California State buildings with pressure-treated glued laminated structural beams have been exposed to pentachlorophenol levels which may have caused physiological irritation. Levin (60) stated that sealing this wood with two coats of polyurethane would reduce exposure substantially. The AWPI (78) has recommended ventilation or sealers as a solution to pentachlorophenol exposure due to interior use of treated wood.

Roberts Consolidated Industries (20) also requests that interior use of 5% pentachlorophenol-based water repellent wood preservative, which binds to wood cells and does not migrate, be allowed with subsequent sealer usage. The Jenson-Wright Corporation (37), which manufactures and seals creosote-treated and pentachlorophenol-treated wood block flooring with coal tar pitch and urethane, states that the Agency has not presented data which make this proposed regulation necessary.

The Missouri Department of Agriculture (28) and the Forest Products Association of Missouri (39) contend that the proposed treatment of the bottom six inches of stall skirtboards, which measure four to five feet high, is unreasonable and impractical; this area would soon be covered with dirt.

The AWPI (36B) and the NFPA (36B) state that the prohibition of applying pentachlorophenol to wood intended for indoor use would severely restrict pentachlorophenol use in farm, storage and public buildings where the low volume of pentachlorophenol-treated wood, sealant usage and lack of prolonged occupancy of public buildings precludes health risks. These commenters suggest that the Agency prohibit interior use over large surface areas, except for cases in which sealants are used; support structures, subject to decay, should also be excluded (AWPI, 36B and NFPA, 36B).

The AWPI (36C) believes that the prohibition of inorganic arsenic-treated wood intended for indoor use should apply to brush-on inorganic arsenicals, excluding this usage for machined, pressure treated wood.

Koppers Company, Inc. (89) and AWPI (36C) commented that the Agency should allow arsenic-treated wood for all interior uses where wood is subject to decay or termites.

However, other commenters state that the risks of indoor use of treated wood warrant the proposed restriction. Nebraska Cooperative Exterior Service (51), Friends of the Earth (FOE) (64 and 70), Center for Disease Control (CDC) (69) and the NFPA (75) support the restricted interior use of treated wood. The FOE (70), CDC (69), and California Department of Health Service (Jackson and Stratton, 87) comment that breathing pentachlorophenol-treated wood fumes, including log homes, can result in skin, respiratory and nervous system disorders as well as relatively high blood and urine pentachlorophenol levels. Portland Cement Association (66) requests that in order to reduce health hazards, arsenic-treated all-weather wood foundations be included in these restrictions.

Agency Response:

Although the benefits of preserved wood for glued laminated structural members may be greater than the Agency originally thought, these commenters did not provide, and (as at the time of the PD 2/3) the Agency is unaware of data allowing quantitative benefits estimates (Eckerman, 1981).

The Agency has revised its risk estimates concerning indoor usage of pentachlorophenol treated wood. Estimates for pentachlorophenol treated wood are based on revised daily exposure [International Symposium on Indoor Air Pollution Health and Energy Conservation, 1981 and the AWPI (36B), 1981] and volatilization information provided by USDA (1981), the AWPI (36B) and the NFPA (36B) (Day, March, 1982 5/82/May 1982, and Dec. 1983). Based on these revised estimates, as well as sealer information (USDA, 1981) and comments from the AWPI (36B) and the NFPA (36B), the Agency has concluded that pentachlorophenol-treated wood should not be used in residential, industrial, or commercial interiors except for lamintated beams or building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied. Creosote-treated wood should not be used in residential interiors. Creosote-treated wood in interiors of industrial buildings should only be used for wood-block flooring and industrial building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied. (See Section VI.E.9 and VI.H., and A.4. for more detail.) For use of treated wood in farm buildings, see Section VII.A.5 for restrictions dealing with the potential for cribbing or licking treated wood. Pentachlorophenol or creosote treated wood may be used where animals cannot crib (bite) or lick the wood, only if a sealer is used.

The Agency will allow industrial use of creosote pressure-treated wood block flooring if an appropriate sealer is used. The model CIS contained in Section VII.C of this PD 4 summarizes the restrictions on interior use of treated wood.

For inorganic arsenical-treated wood, revised estimates were based on exposure data submitted by Koppers (Nov. 15, 1983). Based on these estimates, waterborne arsenic-treated wood may be used inside residences as long as the wood surfaces are vacuumed, thus reducing exposure to arsenic-laden dust. The Agency will also allow brush-on treatments of the inorganic arsenicals for the cut-ends of arsenic pressure-treated wood. In estimating risk to residents of homes containing arsenic-treated wood, the Agency assumed an arsenic air concentration of 0.004 ug/m^3 based on Koppers (Nov. 15, 1983).

The estimated upper limit exposure and risk are summarized in "Appendix B and Appendix C. USDA (1980) indicated that the maximum arsenic air level in homes constructed with masonary basements was 0.019 ug/m^3. This value does not significantly differ from that found for homes with all-weather-wood-foundations; it is lower by less than a factor of 2. The Agency has concluded that the benefits of use of all-weather-wood-foundations outweigh the estimated upper limit risk and that if surfaces are cleaned, arsenic pressure-treated wood may be used in interiors of residences.

Comment Issue #9: Restricted use pesticide classification

Several commenters object to restricted use classification of creosote for home and farm use: the Gibson-Homans Company (3), Coopers Creek Chemical Corporation (4), National Solvent Corporation (6), National Paint Center (7), Soult Wholesale Company (8), Dries Building Supply Company (11), Sampson Paint Manufacturing Company Inc. (12), Standard Concrete Products Company (13), Lloyd H. Daub, Inc. (15), Hatboro Lumber and Fuel Company (16), Doylestown Lumber and Millwork Company (19), C.A. Niece Company (21), GAF Supply Center (22), RAECO Products (23), Monsey Products (25), Michlin Chemical Corporation (29), Carson's Hardware (38), G.M. Deck & Sons (47), Ecological and Speciality Products, Inc. (56), Walpole Woodworkers (57) and The Reliance Company (59). Iowa-Illinois Gas and Electric Company (50) and Osmose (41) disagreed with restricted use classification of all creosote products for poles groundline while the Association of American Railroads (34) does not agree with the Agency's restricted use classification for crossties treatment.

The Agency received comments concerning pentachlorophenol restricted classification for home and farm use (Michlin Chemical Corporation, 25), pressure treatment use (Missouri Department of Agriculture, 28), use on adzed crossties (Association of American Railroads, 34), poles-groundline use (Osmose, 41 and Iowa-Illinois Gas and Electric Company 50) as well as non-site/use specific comments on pentachlorophenol restricted classification (Arneson Timber Company, 46 and McPhillips Manufacturing Company, 49). Nebraska Cooperative Extension Service (51) approved of the restricted use classification.

The AWPI (36C) agreed with the restricted use classification for brush-on inorganic arsenicals, but commented that restricted use classification for sodium pentachlorophenate is unnecessary since EPA-proposed work practices would eliminate exposure.

Agency Response:

The Agency is concerned that home and farm (creosote and pentachlorophenol), poles groundline (creosote and pentachlorophenol) and brush-on (inorganic arsenicals) application of wood preservatives by untrained applicators will lead to potentially unacceptably high risk for such users. The Agency continues to be concerned about the potential oncogenic and mutagenic risks for creosote, the potential oncogenic and teratogenic/fetotoxic risks for pentachlorophenol (MOS=12 for home and farm use even with protective gloves), and the potential oncogenic and teratogenic risks for the inorganic arsenicals. After review and analysis of all available data and information, the Agency believes the potential risks associated with exposure to wood preservatives mandate a restricted use classification with one exception. The Agency has determined upon reevaluation of certain exposure situations, that the restricted use classification is not necessary for inorganic arsenical brush-on treatments to the cut-ends of arsenic treated wood during commercial construction. Moreover, the Agency has determined that the restricted use classification should also be required in light of the potential oncogenic and teratogenic/fetotoxic risks from uses of sodium pentachlorophenate (see Section VI and VIII for modifications to the terms of registration for the wood preservatives). Appendix B presents a summary of the quantifiable risks associated with pentachlorophenol and the inorganic arsenicals.

Comment Issue #10: Restriction of wood preservative products with greater than 5% pentachlorophenol active ingredient

The AWPI(36B) and the NFPA (36B) request that the pentachlorophenol restriction be modified to 6% technical pentachlorophenol products since over-the-counter products contain 5.3%-5.5% technical pentachlorophenol. Osmose (41) states that this restriction is unnecessary because products containing pentachlorophenol are sold "over-the-counter," therefore, classifying these products as restricted use pesticides would do little in the way of reducing exposure.

Agency Response:

The Agency has recalculated the pentachlorophenol risk using a multistage oncogenic risk model and determined, based on these revised data, that the potential oncogenic risks associated with pentachlorophenol are higher than originally calculated. The potential teratogenic/fetotoxic risks are also higher than those estimated in the PD 2/3 due to changes in the exposure estimates as described in Section II.B.2 of this document. Because of these high potential risks, the Agency has concluded that all wood preservative products containing pentachlorophenol must be classified for restricted use by certified applicators or must be applied under the supervision of a certified applicator. For a detailed review of the risk model see Section II.A.3. A comparision of the PD 2/3 potential risk estimates with the current risks is provided in Appendix B.

Comment Issue #11: Labeling of treated wood

Several commenters were opposed to the implementation of a labeling rule under the Toxic Substance Control Act (TSCA). National Woodworks, Inc. (24) does not understand the need to label their millwork products while the Association of American Railroads (34) state that such an action would be impractical. The Missouri State Department of Agriculture (28) and the Forest Products Association of Missouri (39) comment that the Agency is holding wood treaters responsible for end-use of these products. Edison Electric Institute (35) comments that as end users all utility companies would be required to comply with labeling precautions.

The AWPI (36A, 36B, and 78) and the NFPA (36B) comment that labeling under the Toxic Substances Control Act (TSCA) would be costly, inflexible, ineffective and would invite product liability suits (e.g., allegations of negligence); that disposal controls should be promulgated under the Resource Conservation and Recovery Act (RCRA); and that a voluntary program would be faster and more efficient.

Edison Electric Institute (35) comments that the end-use hazards are not sufficient to warrant TSCA-action. The AWPI (36A, 36B and 78) and the NFPA (36B) state that long-term risks associated with treated wood usage are unknown. The AWPI (36C) also comments that the TSCA labeling recommendations concerning protective clothing and dust masks for handling and/or sawing arsenic-treated wood, interior usage of arsenic-treated wood and the use of arsenic-treated wood for vegetable stakes, mushroom trays, feedlots and feed bins is unnecessary because there are no exposure problems associated with these uses.

Friends of the Earth (FOE) (64) contends that any proposed warning that is voluntary would be unsatisfactory. Also, FOE (64) suggests that any consumer awareness information include the fact that pentachlorophenol contains dioxin.

Agency Response:

The Agency agrees that it is unreasonable to expect the wood treaters to know how their products will be used. However, the Agency believes end-users of treated wood should be informed about the safe handling, use and disposal of treated wood. The Agency recommended several labeling regulations enforceable under Section 6 of the Toxic Substance Control Act (TSCA) in the PD 2/3. Promulgating such regulations would take three to five years. As an alternative, the wood preserving industry, representated by AWPI and SAWP, developed a "Consumer Awareness Program" (CAP) to inform the public about proper use and handling of treated wood. Because of this need to inform end-users of the hazards associated with using treated wood, and because the Agency views the "successful implementation" of the CAP as a viable mechanism for achieving this objective, the CAP will be required as a condition of registration. Wood treaters will be required to participate in a Consumer Awareness Program including the distribution of a Consumer Information Sheet (CIS) with each shipment of pressure-treated wood throughout the chain of commerce. The program requirements are detailed elsewhere in the document (see Section VII.C). Statements in the CAP regarding disposal of treated wood are consistent with RCRA.

Utility companies, as end-users of treated wood, are expected to acknowledge and comply with the regulatory precautions described in the CAP to minimize risks to utility workers.

The Agency believes that the risks associated with interior use, handling and sawing arsenic-treated wood warrant the suggested protective requirement. (See Sections VII.A.4 and VI.F for details.) Inorganic arsenicals are not presently authorized for uses where they may become components of food and feed. Registrants must petition the FDA for such a provision.

Comment Issue #12: Closed emptying and mixing system required for all prilled (granular) or flaked formulations of pentachlorophenol and for powdered sodium pentachlorophenate

Michlin Chemical Corporation (25) contends that there is no hazardous exposure associated with their manufacturing process. In order to make pentachlorophenol preservatives from prilled/granular raw material, Michlin Chemical (25) calculates that the 1980 total exposure time equaled 50 minutes (10 batches made at 5 minutes per batch to open and empty bags), with applicators wearing protective clothing and respirator.

The International Woodworkers of America (IWA) of Oregon (63) and Washington (68) contend that the exposure and risk associated with mixing warrants closed systems.

The AWPI (36B) and the NFPA (36B) suggest that persons engaged in mixing pentachlorophenol or sodium pentachlorophenate wear protective clothing and a respirator if the airborne level exceeds an 8-hour threshold limit value (TLV) of .5 mg/m^3. The AWPI (36B, 78) and the NFPA (36B) also suggest that treaters be allowed the option of either protective clothing and respirator or a closed system, in order to avoid imposing an adverse economic impact on small treatment operations.

Michlin Chemical Corporation (25) states that a "closed system" is not defined.

Agency Response:

The Agency has evaluated exposure time associated with opening and emptying bags of powdered pentachlorophenol formulations and has revised its PD 2/3 exposure estimates from four hours/day for five days/week, to a maximum of two hours/day for two days/week. With use of closed systems, exposure will be comparable to ambient levels. If protective clothing and respirators are used, the Agency's re-evaluation of risks indicates that the oncogenic risk will be sufficiently reduced to a level where benefits exceed risks, taking into account that the risk is based on a maximum exposure time (see Section VI.C.3).

To minimize the economic impact of installing closed systems for mixing prilled/flaked formulations of pentachlorophenol and for powdered sodium pentachlorophenate formulations, the Agency is requiring that these systems be "phased in" over a three-year period, with their use becoming mandatory after September 1, 1987, for mixing and emptying prilled or flaked formulations of pentachlorophenol and for powdered sodium pentachlorophenate.

Closed systems are defined as any containment which prevents release of subject chemicals into the surrounding external environment thereby preventing human exposures above ambient air levels (PD2/3, p. 528).

Comment Issue #13: Regulation of applicator vs. handler and end-user

Consumers Power Company (31) contends that there should be logical, practical rules for applicators who are exposed during a majority of the workday. They further comment that handlers and end-users, whose exposure is relatively much less than applicators, should adhere to less stringent regulations minimizing inflationary and productivity impacts.

Osmose (41) requests clarification of the term "applicator" as a person who is actually applying the wood preservative; since the exact terminology used will affect the risk estimates.

Agency Response:

Protective measures are based on estimated exposure and risks for the various uses of wood preservatives. That is, the wood preservative applicator, whose inhalation and dermal exposure would be greater than an individual handling dry treated wood, will be required to adhere to more stringent protective regulatory measures. The Agency also concludes that the requirements for the handler and end-user of treated wood minimally affect worker productivity while providing necessary protection against health hazards.

The Agency considers all workers associated with the treatment proces to be "applicators" regardless of their individual activities during the work day (PD 2/3 p. 577). Wood treatment plant workers perform varied activities during the work day, and may be directly exposed to the wood preservatives as a result of the treatment process.

Coment Issue #14: Prohibition of eating, drinking and smoking during application of wood preservatives

The Association of American Railroads (34), the AWPI (36B, 36C) and the NFPA (36B) and Osmose (41) request clarification of this prohibition concerning the extent of area limitation and "clean" area.

Agency Response:

The Agency has clarified its label language in order to alleviate any wood preservative misuse, and potential subsequent exposure, which could occur due to any ambiguous label language. Section VIII summarizes all mandatory label statements.

Comment Issue #15: Classification of selected non-pressure treatment uses of wood preservatives

Edison Electric (35) is concerned that the Agency has not proposed specific standards for the brush-on application of pentachlorophenol or creosote solutions other than for home and farm use. The Association of American Railroads (71) contends that pentachlorophenol and creosote brush-on/spray application, if considered a home and farm use, should not be restricted by the Agency because of the low spray drift potential. The U.S. Department of Energy (44) questions the Agency concerning the application classification (e.g., poles-groundline, home and farm) of their programs, which include powerline pole inspection and necessary subsequent treatment.

Agency Response:

Utility workers who treat wood will be subject to the same regulations as other applicators and must be certified or under the direct supervision of a certified applicator. The Agency is requiring that all railroad industry applications of pentachlorophenol and creosote be made by workers who are certified or who are under the direct supervision of certified applicators. The U.S. Department of Energy workers will be subject to the same regulations as other poles-groundline applicators.

Comment Issue #16: Restricted use of pentachlorophenol for millwork

McPhillips Manufacturing Company Inc. (49) challenges the need for restricted use classification of pentachlorophenol for millwork. This commenter states that the PD 2/3 fails to recognize differences in the hazards associated with handling wet pentachlorophenol for millwork treatment vs. dry pentachlorophenol-treated millwork products.

Agency Response:

The Agency maintains, as in the PD 2/3, that applicators untrained in the safe handling practices of pentachlorophenol for millwork could have greater exposure than trained applicators. Therefore, pentachlorophenol for application to millwork will remain a restricted use.

Upon reconsideration of information concerning use of pentachlorophenol treated millwork, exposure, and sealers, the Agency has determined prohibition of interior uses of millwork with outdoor surfaces is unnecessary. Use of treated millwork is necessary to prevent mold or insect infestation. Because millwork is usually painted or varnished, the Agency expects exposure from this use of pentachlorophenol to be minimal. (See Section VII.A.4.)

Comment Issue #17: Regulation of pentachlorophenol and sodium pentachlorophenate spray treatment

McPhillips Manufacturing Company Inc. (49) questions the need to regulate pentachlorophenol in the millwork industry because there are no known employees or end-users suffering physical harm from such usage. Publishers Paper (54) is concerned that pentachlorophenol spray booth operations will be cancelled. However, Oregon and Washington International Wood Workers of America (63 and 68, respectively) recommend mandatory and explicit engineering controls, e.g., spray booths and dip tanks for these uses, which they believe would be more effective long-run measures than personal protective equipment.

Agency Response:

Based on the exposure/risk assessment for sapstain control (sodium pentachlorophenate) and millwork and plywood (pentachlorophenol) the Agency is requiring the spray apparatus be operated to minimize overspray (i.e., no visible mist), be free of leaks, and that individuals in contact with application equipment wear appropriate protective clothing. Based on the risk analysis, respirators would only be required if there is a visible mist. See Sections VI.G and VI.H for a more detailed discussion.

The Agency's regulatory options are designed to minimize risks by economical, technologically feasible, practical mechanisms.

Rebuttal Issue #18: Agency regulation of selected wood preservatives together

McPhillips Manufacturing Company Inc. (49) states that because of the differences in creosote, pentachlorophenol and inorganic arsenicals, each class of wood preservatives should be regulated differently, recognizing different levels of toxicity, application, in-plant handling and end-uses.

Agency Response:

Creosote, pentachlorophenol and inorganic arsenicals comprise the most widely used industrial pesticide wood treatments available (Federal Register Notice, Oct. 18, 1978, Part II) and are often alternatives to one another. The Agency has regulated these three preservatives together to minimize the impact on each individual marketplace. However, the risks and benefits of each wood preserving chemical have been evaluated separately and appropriate regulatory measures determined accordingly.

Comment Issue #19: Alternative wood preservative

Michlin Chemical Corporation (25 and 25A) states that the alternative wood preservatives considered in the Agency's risk/benefit analysis are not adequate substitutes. Louisiana-Pacific Corporation (43) states that latex paint is a suitable alternative for wood preservation without the harmful side effects of the wood preservatives. The Nebraska Cooperative Extension Service (51) claims that an AWPI test indicates that creosote is a superior product for stake decay prevention.

Osmose (41) states that copper naphthenate and tributyl tin oxide (TBTO) can only be considered "test" alternatives and cost much more than pentachlorophenol. Seymour Chemicals, Inc. (52) objects that copper-8-quinolinolate is not adequately addressed as a creosote and pentachlorophenol alternative. Osmose (41) believes that the EPA has not made the necessary differentiation between salt and oxide CCA formulations; ACA and CCA: and FCAP and CCA.

Agency Response:

The Agency has received no new economic data on alternatives which would alter the current regulatory decision. Based on the PD 2/3 benefits analysis, the regulatory restrictions listed in this document will have a relatively minor economic impact on the wood treatment industry.

Copper-8-quinolinolate, while it may be efficacious, does not appear to be economically competitive with creosote and pentachlorophenol (Eckerman, 1982). The Agency agrees with the comments that the alternatives to the three wood preservatives used for risk/benefit analysis are not adequate substitutes in all cases; however, factors such as efficacy and cost of alternatives were considered when evaluating the benefits of wood preservatives.

The comment concerning latex paint is very general. Paint would not be considered suitable for wood preservation in situations involving ground contact of treated wood. Also, paint allows moisture to penetrate the wood but does not allow for water to escape.

With respect to creosote alternatives, pentachlorophenol brush-on treatment does have the same efficacy as creosote brush-on treatment (USDA, 1980). Also, all stake decay tests have been factored into the benefits estimate.

Comment Issue #20: Exterior use of treated wood

Portland Cement Association (26) recommends that the proposed prohibition of interior use of inorganic arsenical-treated wood be extended to exterior uses (e.g., patios, decks and chairs), and in lieu of this action, protective materials should be required on these sites. The AWPI (36B) and the NFPA (36B) contend that pentachlorophenol-treated millwork with outdoor exposure should be excluded from regulation.

Agency Response:

Based on a negligible dermal absorption estimate for dry, inorganic arsenic-treated wood and 0.1% dermal absorption estimate for arsenic-treated wood which subsequently becomes wet (Day, 1983), sealers are considered unnecessary where dermal contact is the exposure of concern. As explained in Section VII.A.4, the Agency will not impose regulations on pentachlorophenol-treated millwork in interiors; the exposure is assumed to be minimal, since millwork is normally painted or treated with a sealer, such as shellac.

Comment Issue #21: EPA jurisdiction

Kerr-McGee Corporation (33) contends that the EPA's proposed regulations are within OSHA's jurisdiction, while the U.S. Department of Energy (44) more specifically states that comprehensive OSHA groundline treatment standards already exist. The AWPI (36E) contends that the Agency's labeling program is an intrusion on other regulatory agencies' responsibilities and that the proposed end-use restrictions are beyond the scope of FIFRA (36B and 36C).

Agency Response:

FIFRA authorizes regulation of pesticidal uses, in order to prevent unreasonable adverse effects to the environment including man. The Agency is concerned about notifying consumers of certain potential risks associated with exposure to the pesticides in treated wood, and will promulgate a rule under TSCA if the mandatory Consumer Awareness Program is ineffective.

The EPA has coordinated with other Federal agencies of concern (e.g., Food and Drug Administration, Occupational Safety and Health Administration) and has defined, by inter-agency agreement or by mutual jurisdictional interpretation, EPA's regulatory responsibilities. In a memorandum to EPA dated November 8, 1979, OSHA states "that it will defer to EPA on workplace regulation of uses and impregnation/application so long as OSHA has full assurance from EPA of an active program in that agency to investigate any public or occupational health risks from these wood preservatives that are brought to its attention, and full assurances that regulatory action to eliminate any significant risks also will be forthcoming from EPA." Therefore, the worker protection requirements specified in this document pursuant to FIFRA provide no means of regulating occupational safety and health hazards except insofar as they are directly associated with use of a registered pesticide. The EPA has made no attempt to regulate any workplace hazard except those associated with the use of pesticide products containing creosote, pentachlorophenol (and its salts) and the inorganic arsenicals as wood preservatives. EPA in developing these worker protection requirements has only considered the hazards directly attributed to the use of these pesticides.

Comment Issue #22: Poles-groundline treatment

Edison Electric Institute (35) comments that poles-groundline treatment extends 15-18 inches below and 3-6 inches above ground level, as opposed to the Agency's inaccurate statistics of 6 inches above and below ground.

Agency Response:

The Agency accepts this comment; it is consistent with the USDA (1980) estimate of 6 inches above and 16 inches below the ground level.

Comment Issue #23: Support of EPA action

Six commenters registered support of the EPA's acknowledgement of wood preservatives benefits or the Agency's health concerns [Coopers Creek Chemical Corporation (4), Illinois Power Company (5), National Solvent Corporation (6), Monsey Products (23), Consumers Power Company (31), and Walpole Woodworkers (56)]. Six respondents registered approval of EPA's April 14, 1983, proposal to conclude the RPAR [Osmose (61), Georgia Department of Agriculture (62), Louisiana-Pacific Corporation (73), McFarland Cascade (74) the NFPA (75), J. G. Baxter and Company (76), Koppers Company (77) and Allied Chemical (79)].

Agency Response: The Agency acknowledges these comments and has considered them in developing the final regulatory position.

Comment Issue #24: The relationship between risk estimates and recommended use modifications

The Dow Chemical Company (32) questions the relationship between calculated pentachlorophenol risk estimates and the recommended handling procedures and use modifications proposed in the PD 2/3.

Agency Response:

It is unclear from the statement whether the commenter is referring specifically to handling procedures and use modifications in the plant or end-uses of treated wood or wood products. Based on the risk estimates calculated by Agency scientists (see Section VI and Appendix B), the required regulatory measures are considered necessary to adequately protect users from health hazards associated with application of wood preservatives.

These risk estimates also warrant dissemination of treated wood handling, use, and disposal precautions to consumers who may not be aware of the potential risks involved with using such wood (Section VII.C).

Comment Issue #25: The environmental fate of pentachlorophenol

Friends of the Earth (64) contends that the Agency has not assessed the environmental fate of pentachlorophenol and registers concern that the dioxins from pentachlorophenol bioaccumulate in the environment. The AWPI (78), however, contends that pentachlorophenol is not an environmental hazard; that it biodegrades in water and soil, does not migrate in soil, and that light biodegrades pentachlorophenol and chlorodioxins to harmless constituents (AWPI, 78). Also, according to the AWPI (78), the U.S. Department of the Interior (Columbia National Fisheries Research) has shown (although no data were submitted with comment) that pentachlorophenol accumulation by fathead minnows is minimal and that plants in an open exposure are not adversely affected by pentachlorophenol-treated wood (AWPI, 78).

Agency Response:

The PD 1 on wood preservatives contains readily available information concerning evidence of pentachlorophenol in the air, water, soil, plants and animals. Pentachlorophenol and its degradation products, including dioxins, are known to persist in the environment. According to the comment submitted by the AWPI (Crosby 1980), pentachorophenol and degradation products have been shown to be persistent in bottom sediments after accidental spillage (Pierce, 1978; Pierce, et al., 1977).

Comment Issue #26: Engineering controls and other requirements for the arsenic pressure treatment process.

The AWPI (36C) comments that the wood industry has a clean wood standard. The American Wood Preservers Association (AWPA) does not prescribe methods which treaters must use to meet these standards because judgments concerning cleaning methods should be left to individual applicators (AWPI, 36C). AWPI

(36C) comments that a final vacuum step would adversely affect treatment of some commodities. Osmose data (1980) shows clean wood can be produced without these costly processes (AWPI, 36C). Post rinsing and sheds would be both unnecessary and uneconomical requirements (AWPI, 36C).

Agency Response:

The Agency has reevaluated its PD 2/3 proposal and has determined that the public will be protected if industry standards for clean wood are required. The revised label will include a requirement that the pressure treatment used to apply inorganic arsenical formulations that leave no visible surface deposits on the wood, as defined by the AWPA Standard C-1 and the American Wood Preservers Bureau (AWPB) Standard, LP2 and LP22. Visible surface deposits means that the treated wood shall not have surface residue or crystallization.

VI. FINAL AGENCY POSITION AND RISK/BENEFIT DETERMINATIONS

This section presents the Agency's final regulatory position regarding the pesticidal uses of the three wood preservatives. This Section is organized as follows:

A) upper limits for hexachlorodibenzo-p-dioxin (HxCDD) contamination in technical pentachlorophenol and pentachlorophenol salts;
B) teratogenicity/fetotoxicity warning on all labels for products containing pentachlorophenol or pentachlorophenol salts;
C) pressure-treatment uses of all three wood preservatives;
D) poles-groundline uses of pentachlorophenol and creosote;
E) home and farm (including railroad tie repair) uses of pentachlorophenol and creosote;
F) brush-on treatments of the inorganic arsenicals;
G) use of pentachlorophenol salts for sapstain control; and
H) non-pressure treatment plant dip/flow and spray uses of pentachlorophenol.

Each of those sections (VI.A through VI.H) describes the exposure situation of concern and the estimated potential oncogenic and teratogenic risks, the PD 2/3 proposal to reduce the risk, comments and/or new information received since the PD 2/3 was published, and the Agency's basis for the final regulatory position.

A. Upper Limits for Hexachlorodibenzo-p-dioxin (HxCDD) Contamination in Technical Pentachlorophenol and Pentachlorophenol Salts

Exposure/Risk: The estimated potential oncogenic risks for the various use situations where applicators and end-users of treated wood are exposed are summarized in Appendix B of this PD 4 and are discussed in detail below in Sections VI and VII. The potential oncogenic risks from exposure to the HxCDD contaminant in pentachlorophenol and sodium pentachlorophenate without protective measures range from 1.5×10^{-2} for bag emptying activities to 1.0×10^{-4} for home and farm brush-on treatments. The potential oncogenic risks with protective measures range from 2.4×10^{-4} for millwork and plywood spray applications to no risk where interior use of pentachlorophenol is prohibited. Section II.A.2 describes the bases for the Agency's estimation of potential human oncogenic risk.

The Agency assumed in the PD 2/3 that 15 ppm was a representative upper limit for hexachlorodibenzo-p-dioxin (HxCDD) contamination in pentachlorophenol and sodium pentachlorophenate based on data submitted by manufacturers (Rakshpal, 1980; SAB, 1978; and AWPI Rebuttal to the PD 1 #30000/30, 1979). This upper limit was used in the PD2/3 in calculating the potential oncogenic risk from exposure to this contaminant in penta chlorophenol and sodium pentachlorophenate products. Fifteen ppm was also used in this position document (PD 4) for risk estimation in exposure situations without taking into account the protective measures required. The oncogenic risks for the various use situations are summarized in Appendix B of this PD 4.

PD 2/3 Proposal: Because Dow Chemical Company had shown (SAB, 1978) it could manufacture a pentachlorophenol product (Dowicide-EC7) with less than 1 ppm HxCDD, the Agency considered proposing that all registrants lower the HxCDD, the contamination in pentachlorophenol and sodium pentachlorophenate to a maximum concentration of 1.0 ppm (PD2/3, p. 566). However, in the PD 2/3 the Agency decided not to propose that registrants reduce the HxCDD in their products from 15.0 ppm to 1.0 ppm because: (1) The Agency believed that at 15.0 ppm the benefits of use of these products outweighed the risks if certain protective measures proposed in the PD 2/3 were adopted (protective clothing, protective equipment, restricted use) and (2) though Dow had the technical capability to produce pentachlorophenol with less than 1 ppm HxCDD, requiring production conversion by other companies to the purer form might cause them to cease manufacturing this wood preservative because of cost consideration.

Final Agency Position and Rationale: The Scientific Advisory Panel (SAP) reviewed the proposals presented in the PD 2/3 and strongly recommended that "EPA should require industry to reduce the dioxin content of penta to as low a level as is technologically and economically feasible." In addition, since the PD 2/3 was published the potenial estimate risk due to exposure to the HxCDD contaminant in pentachlorophenol products has increased due to modifications in exposure assumptions and risk estimation. These changes were discussed in Section II of this document. Because in some cases, depending on the use situation, the potential risks increased one or more orders of magnitude, the benefits of use of the pentachlorophenol products no longer outweighed the risks; continued use of pentachlorophenol products containing 15 ppm HxCDD would pose unreasonable adverse effects to applicators.

In the light of the SAP recommendations and the increase in risk estimates the Agency has reevaluated its position on regulating the levels of HxCDD contamination.

The Agency has concluded, after evaluating the information available, that the HxCDD contamination in pentachorophenol and sodium pentachlorophenate products must be reduced within 18 months to a level which will not exceed 1.0 ppm. This will reduce potential risks by a factor of 15 (15 ppm reduced to 1.0 ppm HxCDD). Until this limit of 1.0 ppm is achieved, the HxCDD contamination must not exceed 15 ppm. The rationale and justification for the Agency's decision is contained in the paragraphs which follow. This requirement and others presented in this PD 4 are expected to reduce the potential risks due to HxCDD exposure such that there will be no unreasonable adverse effects to man or the environment.

Information reviewed by the Agency indicates that it is technologically feasible to produce pentachlorophenol products which contain no greater than 1.0 ppm HxCDD. A product manufactured by Dow Chemical Company, Dowicide EC-7, has been shown by chemical analysis to contain less than 1.0 ppm HxCDD. Data supporting this has been summarized by Rakshpal (1980) and the Science Advisory Board (SAB, 1978). AWPI (Rebuttal to the PD1, #30000/30, pp. 52-55, 1979) also summarized data which showed that purified (distilled) pentachlorophenol contained less than 1.0 ppm HxCDD and in some instances contained less than 0.03 ppm.

More recently, Idacon, Inc., has developed a purification method to remove chlorodibenzo-p-dioxin and chlorodibenzofuran contaminants from pentachlorophenol (United States Patent No. 4,228,309, Oct 14, 1980). A description of this method was submitted to the Agency for review by Pazianos Associates (1984). The Agency has evaluated this purification method and has concluded that the process does reduce levels of chlorodibenzop-dioxins and chlorodibenzofurans and theoretically should also reduce other chlorinated impurities such as hexachlorobenzene, though no chemical analysis was presented for the latter (Dodd, March 29, 1984). In its description of the method, Idacon stated that "costs to purify the pentachlorophenol would be in the range of 10 cents per pound of pentachlorophenol" and that, "based on today's market prices for wood preservatives, the added cost would not render pentachlorophenol non-economic as wood preservative." The Agency has no data to substantiate or refute this economic assessment.

In addition, after reviewing published literature on possible manufacturing methods (Pesticides Process Encyclopedia, 1977), the composition of technical pentachlorophenol (Journal of Dairy Science, 1981), and the composition of commercial grade pentachlorophenol and production of impurities (Firestone, 1972), the Agency believes, based on theoretical considerations, that an extraction of an alkaline aqueous solution of pentachlorophenol with a non-polar aromatic solvent could reduce the levels of chlorodibenzo-p-dioxins, dibenzofurans, and hexachlorobenzene at the same time (Dodd, Feb. 24, 1984).

Based on the information cited above, the Agency has concluded it is technologically feasible to substantially reduce the stated impurities in pentachlorophenol products.

The Agency also believes it would be economically feasible to reduce the dioxin content in pentachlorophenol products. The Dow Chemical Company produced and sold Dowicide EC-7 which contained less than 1.0 ppm HxCDD. Dow discontinued the manufacturing of this product in part, as reported by NIOSH (1983), because the purification process was too costly. However, while it may not have been economical for one manufacturer in a competitive market, the Agency believes that requiring all registrants to lower the HxCDD content to levels not to exceed 1.0 ppm would eliminate that cost disadvantage. Costs would be absorbed by the companies and/or passed on to the consumer.

The Agency is aware that although it may be technologically and economically feasible to produce pentachlorophenol and sodium pentachlorophenate products containing no more than 1.0 ppm HxCDD, it will take time to modify the manufacturing process to meet this requirement. During the time these modifications are being made, the Agency requires that the HxCDD contaminant does not exceed the current representative upper limit of 15 ppm. Chemical analyses of HxCDD in pentachlorophenol and sodium pentachlorphenate indicate that it is currently possible to meet a 15 ppm HxCDD upper limit without "purifying" the product. This interim upper limit of 15 ppm will allow the modifications to the manufacturing process to be completed without unwarranted economic disruption.

Rakshpal (1980) summarized data received from Dow Chemical, Reichold, and Vulcan which showed that an upper limit of 15.0 ppm or less HxCDD could be achieved.

The Science Advisory Board (SAB, 1978) and AWPI (Rebuttal to PD1, #30000/30, Appendix 4, pp. 52-55) reported that HxCDD contamination found in a composite sample (excluding the purified Dowicide EC-7) from pentachlorophenol producers was 15.0 ppm or less. SAB (1978, Tables 2.1 and 2.2) also reported HxCDD concentrations of less than 10.0 ppm for Dowicide 7, a commercial "non-purified" pentachlorophenol product. Sodium pentachlorophenate was reported to contain below 4.0 ppm HxCDD (SAB, 1978, Table 2.2). AWPI (#30000/30, 1979 pp. 53-55) also reported HxCDD concentrations below 4.0 ppm for sodium pentachlorophenate.

Reichold Chemicals [83(30000/28C)] also cited data from the SAB report (1978 Tables 3 and 4) showing that Dowicide 7, an "unpurified" product, contained less than 10 ppm HxCDD and that a composite pentachlorophenol sample contained 15.0 ppm HxCDD. This latter figure was also reported in a submission by AWPI [#84 (30000/28C)].

Regarding pentachlorophenol manufacturers in Europe, Buser and Bosshardt (1976) published results of analyses of HxCDD in several pentachlorophenol products purchased in Switzerland. The HxCDD concentrations of all samples were below 10.0 ppm. The Agency has received additional information that two manufacturers of pentachlorophenol in Europe currently consistently achieve below 8 ppm HxCDD contamination without any additional "purification" steps (Dobbs, personal communication, 1984). The average concentration is 4.5 ± 0.6 ppm HxCDD with 95% confidence limits.

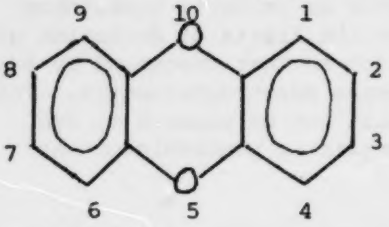
The above cited data indicate it is currently technologically and economically feasible to produce pentachlorophenol and sodium pentachlorophenate products containing 15.0 ppm as an upper limit for HxCDD contamination. Therefore, the Agency has determined that registrants will be required to amend their confidential statements of formula for technical pentachlorophenol and sodium pentachlorophenate products to indicate that the HxCDD contamination does not exceed 15.0 ppm. The confidential statements of formula must be amended within 30 days after the Notice concluding the Wood Presevatives RPAR is published in the Federal Register or within 30 days after receipt of such Notice by the registrant, whichever occurs later. Registrants must also periodically submit HxCDD analyses of their products using an appropriate gas chromatography/mass spectrophotometry method (e.g., Buser and Bosshardt, 1976) approved by the Agency.

Within the stated 30-day period, the registrant must also file an application to amend the confidential statements of formula to reflect that the HxCDD contamination does not exceed 1.0 ppm, effective 18 months after publication of the Notice or receipt by the registrant, whichever occurs later. The Agency believes this is a reasonable length of time for the registrants to modify their manufacturing process to meet the HxCDD 1.0 ppm upper limit requirement. Furthermore, within 90 days of publication of the Notice, registrants must submit to the Agency in writing their plan for reducing the HxCDD contaminant to 1.0 ppm or lower.

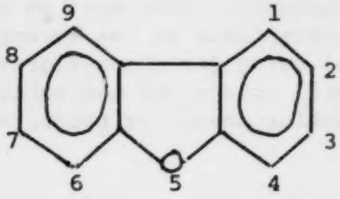
In addition to the chlorinated dibenzo-p-dioxins, chlorinated dibenzofurans have also been shown to be contaminants of pentachlorophenol products (Position Document 1, 43 FR 48443 and PD 2/3, p. 16). Levels of contamination of the two chemicals parallel each other; i.e., high levels of dibenzo-p-dioxin are associated with high levels of dibenzofuran (PD 1, 43 FR 48443, Buser and Bosshardt, 1976; Rappe, 1981; PD 2/3, p. 348). The chlorinated dibenzofurans have been shown to be highly toxic in laboratory animals (Moore et al., 1979; Buser and Bosshardt, 1976; Rappe, 1981). Like the dioxins, they cause characteristic edema, weight loss and liver toxicity in laboratory animals prior to death (McConnel and Moore, 1979)

In addition, tests of liver enzyme induction by chlorinated dibenzofurans in hybrid mice (Poland et al., 1979) have shown that these chemicals are similar to chlorinated dioxins in their response.

The chemical structures of the chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans are similar (Buser and Bosshardt, 1976).



Dibenzo-p-dioxin



Dibenzofuran

Chlorine may be attached in various combinations, at the 1,2,3,4,6, 7,8, and 9 positions (Buser and Bosshardt, 1976).

Because of the structural similarity and because of their functional similarity in short term testing, the Agency is concerned that, although there are no chronic long term studies, chlorinated dibenzofurans could be potential human oncogens as are the chlorinated dibenzodioxins.

Therefore, the Agency requires that the method used by registrants to lower the HxCDD content must not increase the chlorinated dibenzofuran contamination.

Another contaminant in pentachlorophenol products is hexachlorobenzene (HCB), shown in the PD 2/3 (p. 345) to be an oncogen in laboratory animals. The potential oncogenic, reproductive, and teratogenic/fetotoxic risks associated with exposure to HCB were presented in the PD 2/3 (pp. 345-346, 354-365).

Using the "one-hit" model of risk assessment, the oncogenic potency (slope) was calculated to be 0.0027 $(\mathrm{ug/kg/day})^{-1}$ (PD 2/3, p 365). Though HCB is a less potent oncogen than HxCDD as indicated by the slope calculated for HxCDD in the PD 2/3 [HxCDD slope=6.2 $(\mathrm{ug/kg/day})^{-1}$], the Agency is concerned about possible increases in this contaminant as well.

Therefore, the Agency requires that the method used by registrants to lower the HxCDD contamination must not increase the HCB contamination.

The Agency believes that it is prudent and reasonable to require that registrants reduce HxCDD, and not increase the chlorinated dibenzofurans and HCB contaminants in pentachlorophenol and sodium pentachlorophenate products to protect the public from potential unreasonable adverse effects. Theoretically, these three impurities can be reduced by the same purification or extraction process during manufacturing (Dodd, 1984). By reducing the HxCDD from 15 ppm to 1.0 ppm, the potential oncogenic risks to applicators will be reduced by more than an order of magnitude.

The most highly toxic dioxin is 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) (Nicholson and Moore, 1979). Although it has not been found in analyses of samples of pentachlorophenol (Buser and Bosshardt, 1976; SAB, 1978; Rakshpal, 1980), the Agency has concluded that registrants must amend the confidential statements of formula to indicate that 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) is not found in pentachlorophenol products or products containing salts of pentachlorophenol. TCDD must be below the limits of detection of analytical methods acceptable to the Agency, such as that described by Buser and Bosshardt (1976) using gas chromatography-mass spectrophotometry. This regulatory action will ensure tht the public will not be exposed to TCDD when applying pentachlorophenol or products containing pentachlorophenol salts.

Because manufacturing process and product chemistry data are lacking for technical pentachlorophenol and its salts, the Agency will require, in a separate action, that registrants submit "additional data to support existing registrations" pursuant to Section 3(c)(2)(B) of FIFRA, in order to maintain in effect existing registrations.

To summarize, the Agency has concluded that, in order to avoid posing an unreasonable adverse effect to the environment, registrants of products containing technical pentachlorophenol or its salts must meet the following two requirements (among others presented in this position document) within 30 days of publication of the Notice concluding the Wood Preservatives RPAR in the Federal Register, or within 30 days of receipt of such Notice by the registrant, whichever occurs later:

1. File an application to amend the confidential statements of formula (CSF) for products containing technical pentachlorophenol or its salts to indicate that the HxCDD contamination does not exceed 15 ppm and that 2,3,7,8-TCDD is below the limits of detection, using a gas chromatography-mass spectrophotometry method acceptable to the Agency (e.g., Buser and Bosshardt, 1976).

2. File an application to amend the CSFs for products containing technical pentachlorophenol or its salts to indicate that effective 18 months after publication of the Notice or receipt by the registrant (whichever occurs later) the HxCDD contamination does not exceed 1.0 ppm. (The method used to lower the HxCDD levels to 15.0 ppm or 1.0 ppm or lower must not increase the hexachlorobenzene or the chlorinated dibenzofuran levels above the levels in products marketed at the time of publication of the FR Notice.)

In addition to complying with the above requirements, the registrants of products containing technical pentachlorophenol or its salts will be required in an action separate from this PD 4, to submit the following to maintain in effect existing registrations pursuant to FIFRA Section 3(c)(2)(B):

1. A description of the starting materials, manufacturing process and reaction conditions including any steps to reduce HxCDD.

2. Information on product identity relative to identification of ingredients, statement of composition and a discussion of the formation of impurities.

3. Data on the analysis and certification of product ingredients relative to preliminary analysis, certification of limits, and analytical methods for the enforcement of limits. An analytical method employing combined gas chromatography and mass spectrophotometry is acceptable (e.g., Buser and Bosshardt, 1976).

4. HxCDD analyses every three months, the first analysis to be submitted within the stated 90-day period.

5. A description of any changes in the manufacturing process used to lower HxCDD to 15 ppm and/or 1.0 ppm or lower must also be submitted within the stated period of 90 days. (The methods used to lower HxCDD must not increase the chlorinated dibenzofurans and HCB contaminants above the levels in products marketed at the time of publication of the FR Notice.)

6. Information on the technical feasibility and costs of reducing the HxCDD contamination further than the 1.0 ppm upper limit.

These requirements satisfy the SAP recommendation that "industry reduce the dioxin contamination in penatachlorophenol to as low a level as is technologically and economically feasible." These requirements and other requirements presented throughout this document to reduce the risks (e.g., protective clothing and equipment, restricted use) fulfill the congressional mandate as outlined in FIFRA to regulate the use of pesticides so that there will be no unreasonable risk to man or the environment.

To recalculate the potential oncogenic risks without protective measures for pentachlorophenol and sodium pentachlorophenol in this PD 4, the Agency assumed that the upper limit of HxCDD contamination was 15 ppm; to recalculate risks with protective measures (e.g., HxCDD reduction, protective clothing, respirators), the Agency assumed that the HxCDD upper limit was 1.0 ppm. The recalculated PD4 risks presented throughout this document reflect this assumption.

As reported in the PD 2/3 (pp. 16-17), the forms of chlorinated dibenzo-p-dioxins most commonly found in pentachlorophehol (including its salts) are hexa, hepta, and octachlorodibenzo-p-dioxins. A small amount of tetrachlorodibenzo-p-dioxin (TCDD) has also been found, but this is not the highly toxic 2,3,7,8-TCDD. The chlorinated dibenzofurans found in pentachlorophenol are the tetra, penta, hexa, hepta, and octachlorodibenzofurans. The Agency believes that the requirements for exposure reduction described in this PD 4 with which the registrants must comply will serve to reduce the chlorinated dibenzo-p-dioxins and the chlorinated dibenzofurans to levels which will not pose unreasonable adverse effects to the environment.

B. Teratogenicity/Fetotoxicity Warning on All Labels for Products Containing Pentachlorophenol or Pentachlorophenol Salts.

Exposure/Risk: As described in the PD 1 (43 FR 48443) and PD 2/3 (pp. 347-356) studies have shown that administration of pentachlorophenol to laboratory animals is associated with fetotoxic effects, H_xCDD with teratogenic and fetotoxic effects, and HCB with teratogenic, fetotoxic, and reproductive effects. These studies are summarized in the paragraphs which follow.

Pentachlorophenol. The study of Schwetz et al. (1974) showed that either commercial or purified pentachlorophenol, when administered by gavage to rats on gestation days 6 through 15, caused statistically significant increases in fetal resorptions, altered sex ratios, and decreases in fetal body weight and crown-rump length at the higher doses tested. Significant increases in fetal anomalies (compared to controls) were observed for skeletal defects of the ribs, sternebrae, and vertebrae, at the two highest dose levels of both purified and commercial penta. The lowest dose of purified penta (5 mg/kg/day) caused an increase in delayed skull ossification. The Agency believes the delayed skull ossification observed at this level is significant.

Due to lack of an adequate NOEL in the study of Schwetz et al. (1974), the Agency chose the one-generation study of Schwetz et al. (1978) for purposes of risk assessment. In this study, parental rats were given dietary administration at 3 and 30 mg/kg/day. At the 3 mg/kg/day level the data show a trend toward decreased neonatal weight (consistent with the high dose) which continues as the animals age. At any individual measurement period, however, this neonatal weight decrease at 3 mg/kg/day is not statistically significant. At the highest dose there was "a significant decrease in the percent of pups born alive, as well as significant decreased survival to days 7, 14, and 21 of lactation." The average litter size after treatment at the highest dose also was significantly lower than among controls on days 7, 14, and 21 of lactation. Treatment at the high dose caused a significantly increased number of litters with variations in lumbar spurs and vertebrae with unfused centra.

The data of Schwetz et al. (1978) are adequate to establish a provisional NOEL for the fetotoxicity of the pentachloropenol studied.

As more fully described in the PD-2/3, other toxicity parameters also exhibit NOELs near or somewhat below 3 mg/kg/day. Female rats dosed dietarily with 1.5 mg/kg/day of technical penta (Goldstein et al., 1977) showed a 15-fold increase over controls in the activity of aryl hyrdocarbon hydroxylase (AHH) and a significant elevation of glucuronyl transferase activity. Although the toxicological meaning of these elevations is not clear, an elevated AHH activity has been used as a "biochemical correlate" for the presence in biological samples of some of the non-phenolic contaminants of technical pentachlorophenol.

It is also noted in the PD 2/3 that at the level of 3 mg/kg/day (or somewhat lower) there exist systemic or organ-specific NOELs in rats exposed to chronic or subchronic treatment. The two-year study of Schwetz et al. (1978) reports body weight and food consumption changes in the adults. For subchronic toxicity, Kimbrough and Linder (1978) reported mild histopathologic effects in the liver of rats treated at 1.5 mg/kg/day. The 90-day feeding study of Kociba et al. (1973) reported decreased testes-to-body weight ratios at all doses, including significantly lower ratios at 1.0 mg/kg/day. In the 90-day rat feeding study of Knudsen et al. (1974), the liver-weight increase in females was dose related and significant at 2.5 mg/kg/day. A third 90-day rat feeding study (Johnson et al., 1973) reported a NOEL of 3 mg/kg/day, based on increased liver weight at higher doses. Results of 90-day feeding studies are useful for comparison with fetotoxic effects which may occur with relatively short exposure duration.

HxCDD: The teratogenicity and fetotoxicity of HxCDD is demonstrated in the gavage study of Schwetz et al. (1973), in which pregnant rats were treated on days 6 through 15 of gestation with two (unspecified) isomers of purified HxCDD. At the upper doses there were significant increases above control values in fetal resorptions, dilated renal pelvis, and cleft palate (top dose), as well as decreases in fetal body weight and crown-rump length. Subcutaneous edema was observed at all doses except 0.1 ug/kg/day (low dose), which the Agency adopted as the fetotoxicity/teratogenicity NOEL for HxCDD.

HCB: Courtney et al. (1976) reported teratogenic effects in mice caused by oral administration of 100 mg/kg/day HCB, including cleft palates, elevated maternal liver-to-body weight ratios, and decreased fetal body weights. Khera (1974) reported fetotoxic effects at 40 mg/kg HCB including sternal defects and extra ribs. Simon et al. (1979) found reproductive effects in the rat at 70 or 221 mg/kg/day HCB including a decrease in the number of females inseminated and impregnated. Grant et al. (1977), in a four generation rat reproduction study, found reproductive changes relative to pregnancy, viability, lactation indices, neonatal weight gain, and relative liver weight at a NOEL of 1.0 mg/kg/day dietary HCB.

The NOELs used in the PD 2/3 to calculate margins of safety were:

Pentachlorophenol: 3 mg/kg/day (Schwetz et al., 1978).

HxCDD: 0.1 ug/kg/day (Schwetz et al., 1973).

HCB: 1.0 mg/kg/day (Grant et al., 1977).

The Agency was concerned that applicators of pentachlorophenol in both occupational and home and farm settings were being exposed to these potential risks. By dividing the NOEL by the estimated exposure, the Agency calculated the Margins of Safety (MOS) for these effects and found (PD 2/3, pp. 357-359) that, with no protective measures taken into account, exposure to pentachlorophenol during application posed the greatest potential hazard with MOS's ranging from only 5.9 for dip/flow applicators to 650 for home and farm use; MOS's for HxCDD ranged from only 13 (home and farm) to 330 (opening cylinder door); and MOS's for HCB were all above 10,000.

PD 2/3 Proposal: To provide greater protection from the potential fetotoxic, teratogenic, and reproductive effects of pentachlorophenol and its contaminants, the PD 2/3 proposed requiring protective measures such as gloves, protective clothing, protective equipment, and restrictions on use, depending on the specific exposure situation. With these protective measures the Margins of Safety were increased (PD 2/3, pp. 660-662) and thus the Agency concluded that no unreasonable adverse effects would be posed to applicators using pentachlorophenol products.

Final Agency Position and Rationale:

Since the publication of the PD 2/3, new information as described in Section II of this document resulted in revisions in both exposure and risk estimates for pentachlorophenol. For example, the Agency revised the rates of dermal absorption of pentachlorophenol from 10% (PD 2/3) to 50%, and the protection provided by gloves from 99% (PD 2/3) to 90%. These revisions resulted in lower estimated Margins of Safety than had been calculated for the PD 2/3. As summarized in Appendix B of this PD 4, the MOS for millwork/plywood applicators (dip/flow) and home and farm applicators using protective gloves is 12. The MOS for millwork/plywood spray applicators using gloves and respirators is 23. Applicators in pressure treatment plants use a much more concentrated pentachlorophenol solution (40% vs. 0.5 to 5%) and therefore, though no dermal exposure could be estimated, it would be expected that the Margin of Safety would be lower than 12 for applicators wearing gloves and protective clothing in pressure treatment plants.

Therefore, the Agency has concluded, as described elsewhere in this document for the various use/exposure situations, that all pentachlorophenol and sodium pentachlorophenate products must be restricted to use only by certified applicators and that appropriate impermeable protective clothing must be worn by the certified applicators. In addition, the Agency requires all registrants of products containing pentachlorophenol or its salts to include the following information on the labels:

> The U.S. EPA has determined that pentachlorophenol can produce defects in the offspring of laboratory animals. Exposure to pentachlorophenol during pregnancy should be avoided.

Because women of child-bearing age may be exposed to both occupational and home/farm uses of pentachlorophenol the Agency has concluded it is prudent and reasonable to include the label statement to inform women of the potential teratogenic/fetotoxic hazards. Although no specific risk reduction estimate can be made, the Agency assumes that potential risks from exposure to pregnant women using pentachlorophenol or sodium pentachlorophenate for wood preservation would be reduced if this information is displayed prominently on the label and if use is restricted to certified applicators who must wear impermeable protective clothing.

C. Pressure Treatment Uses: All Three Wood Preservatives

Wood may be preserved by the application of creosote, inorganic arsenicals, and pentachlorophenol either by pressure treatment or non-pressure treatment methods. This Section addresses pressure treatment uses of the three wood preservatives, discusses the PD 2/3 regulatory proposals and the final regulatory position, and presents the bases and rationale for the final position.

Risks are estimated for each of several activities in the treatment plant where applicators are exposed to the wood preservatives. If one applicator performs several activities, the total potential risks to that individual will be higher. Wherever it was possible to estimate both dermal and inhalation risks, the Agency has done so. These estimated risks represent the increased risk of cancer due to exposure to wood preservatives above that of incidences of cancer from other causes.

1. Permissible Exposure Limit (PEL)/Respirators for Inorganic Arsenical Treatment Plant Workers

Exposure/Risk: As discussed in the PD 2/3, applicators or other personnel working outdoors in inorganic arsenical treatment plants are exposed to potentially high air concentrations of arsenic which are distributed throughout the treatment plants. The applicator's inhalation exposure to the ambient arsenic increases when the treatment solution leaches, dries, and flakes from the surface of the drying stacks of freshly treated wood, producing a dust containing arsenic. The Agency was concerned that applicators were inhaling small particles of the arsenic dust and that arsenic was being absorbed in the lung. Larger particles are ingested and are absorbed in the gastrointestinal tract. Based on an air arsenic level of 70 ug/m^3, the Agency estimated in the PD 2/3 (p. 245) that the teratogenic/fetotoxic Margin of Safety (MOS) is 500. The total lifetime oncogenic risk from the background arsenic air levels in the plant was estimated to be 1.9×10^{-2} (PD 2/3, pp. 582, 623, and 644).

PD 2/3 Proposal: To reduce this inhalation exposure, the Agency proposed the following in the PD 2/3:

> Applicators who work outdoors in arsenical wood treatment plants must wear a dust mask capable of trapping 80% of particulates greater than 5 microns in size.

Wearing a dust mask while working outdoors in an arsenical wood treatment plant reduces inhalation and ingestion exposure and results in a total oncogenic risk from exposure to the inorganic arsenicals during this activity of 3.8×10^{-3} (PD 2/3, pp. 624 and 645). The teratogenic/fetotoxic MOS would be 2,500 (PD 2/3, pp. 624 and 653) if a dust mask were worn.

Final Regulatory Position and Rationale: The Agency received new data submitted by AWPI (#36: 30000/28C) in response to the PD 2/3 regarding the arsenic levels to which workers are exposed in the treatment plant.

These data, as described in Section II of this document, as well as data collected and evaluated by OSHA (48 FR 1864), indicated that a more realistic estimate of airborne arsenic in a treatment plant environment was 10 ug/m^3 (PD 2/3 assumed 70 ug/m^3).

The Agency recalculated the oncogenic risks based on the revised exposure estimates for airborne arsenic in a treatment plant environment and revised estimates for the inhalation absorption rate for particulate matter containing arsenic. The Agency compared risks to applicators using dust masks with risks to applicators using respirators. Without inhalation protection the resulting total oncogenic risks, if an applicator is exposed to 10 ug/m^3 (0.01 mg/m^3) of ambient arsenic for an 8-hour work day are 4.1×10^{-3} (Rispin, April 18, 1984). The PD 2/3 estimate was 1.9×10^{-2} based on a 70 ug/m^3 air concentration. If the inorganic arsenic level is unknown, but assumed to be 10 ug/m^3 and the employee wears a dust mask, the total oncogenic risks are reduced to 8.2×10^{-4}, assuming 80% inhalation protection (Kozak, 1980). No new MOS figures were calculated for inorganic arsenic because the Agency has determined as discussed in Section III. B of this document, that there are not adequate data to determine a NOEL.

If the inorganic arsenic level is unknown, but assumed to be 10 ug/m^3 (averaged over 8 hours) and the employee wears a respirator, the total oncogenic risks would be 4.1×10^{-5} as compared with 8.2×10^{-4} if dust masks are worn (Rispin, April 18, 1984). Thus, a respirator gives approximately five times more protection than a dust mask. Respirators are assumed to provide 99% protection against arsenic inhalation (OSHA 29 CFR 1910.1018, Table 1) and dust masks are assumed to provide 80% inhalation protection (Kozak, 1980).

See Appendix B for a comparison of the revised risk estimates with those calculated for the PD 2/3. The risk model used for the calculations was a human dose-response model whereby the risk is linearly related to dose as described in the "Health Assessment Document for Inorganic Arsenic" (U.S EPA, June 1983).

Taking into account the new data, the revised risks, the and the reduction in exposure afforded by a respirator, the Agency has determined that inhalation exposures will be sufficiently reduced such that there will be no unreasonable adverse effects if a Permissible Exposure Limit (PEL) of 10 ug/m^3 averaged over 8 hours is adopted or if respirators are worn. As described in Section II of this document, this is consistent with the Threshold Limit Value (TLV) of 10 ug/m^3 for arsenic adopted by the Occupational Safety and Health Administration (OSHA). The Agency has concluded that registrants must modify their labels to contain the following information:

> Employees in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high

efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10 ug/m^3) averaged over an 8-hour work period. Air monitoring programs, procedures and record retention and submission must be conducted in accordance with the instructions on the attached labeling material.

Employers who elect to monitor air levels (to avoid having workers wear respirators at all times if arsenic air levels are unknown) must complete air monitoring to determine initial levels of airborne arsenic exposure within one year of publication of the final determination concluding the wood preservatives RPAR in the Federal Register, and must repeat monitoring if the initial or subsequent monitoring reveals exposure above 5 ug/m^3 or if certain other conditions exist. The Agency expects that this monitoring requirement may also serve as an incentive for operators of wood treatment facilities to make sure that the ambient air levels of arsenic do not exceed 5 ug/m^3. For a more complete explanation of the implementation of the monitoring program required, see Section VIII.B.3 of this document.

The Agency has chosen the PEL of 10 ug/m^3 average over an 8-hour period as an alternative to requiring respirators to be worn at all times by all applicators who work outdoors in arsenical wood treatment plants because: 1) the option of monitoring to determine ambient levels of arsenic would relieve the workers of the burden of wearing respiratory protection unnecessarily; and 2) the PD 2/3 proposal did not take into account establishments in which the levels of inorganic arsenic were known to be below a specified upper limit. In addition, OSHA based the upper limit of 10 ug/m^3 on both oncogenic risk assessment and technical feasibility considerations.

2. Protective Clothing and Respirators/Entering Treatment Cylinders.

Exposure/Risk: As discussed in the PD 2/3, it is occasionally necessary for a treatment plant applicator to enter a pressure cylinder (e.g., for manual cleaning or releasing a wood jam). During such activity, there is an opportunity for both dermal and inhalation exposure. This potential exposure to the treatment solution exists in all treatment plants, whether creosote, pentachlorophenol, or the inorganic arsenicals are being used for wood preservation.

The risks to applicators resulting from exposure to any of the three wood preservatives during this activity have not been quantified due to a lack of exposure data. However, in the PD 2/3, the Agency assumed for the inorganic arsenicals that the total oncogenic risk to personnel entering the cylinders would be greater than the risks from the background inhalation exposure (1.9×10^{-2}) and the dermal exposure from coming into contact with the diluted solutions (2.6×10^{-2}).

PD 2/3 Proposal: To reduce these risks the Agency proposed for each of the three chemicals that:

> Applicators who enter pressure treatment cylinders and other related equipment wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots, and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.

An applicator wearing this protective clothing and a respirator while performing these activities will have a significantly reduced inhalation exposure (by 90%) and total dermal exposure (by 80%) resulting in significantly reduced risks.

Final Regulatory Position and Rationale for Creosote and Pentachlorophenol: The Agency received information from the wood preserving industry (AWPI, June 17, 1982) about the types of protective gloves, clothing and equipment suitable for applicator protection from creosote and pentachlorophenol, though no actual data were submitted on the permeability of the various protective materials. Data by Silkowski (1982) indicated "break-through" times for certain materials in contact with a pentachlorophenol solution. The data indicated how long the materials could be in contact with the solutions before leaks in the material developed.

As a result of evaluating this information the Agency has revised the PD 2/3 proposal to require additional detail concerning types of respirator and specific materials for protective clothing to be included on the labels. However, this is an interim measure. The Agency, in a separate action pursuant to FIFRA Section 3(c)(2)(B), will require that the registrants provide data on the impermeability of these recommended materials when in contact with creosote. The Agency is requiring certain materials for protective clothing for workers when contacting pentachlorophenol solutions, based on the study by Silkowski (1982). Upon receipt of the permeability data on creosote, the Agency will reevaluate its recommendations for materials considered appropriate for protection against contact with creosote formulations.

The Agency has concluded that, in order that the benefits of pressure treatment uses of creosote and pentachlorophenol exceed the risks, the labels must be modified to contain the following information:

> Applicators who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment formulation (e.g., cylinders that are in operation or are not free of the treatment formulation) must wear protective clothing (including overalls, jacket, gloves and boots) impervious to the wood treatment formulation and respirator.
>
> Respirators acceptable for use by applicators of creosote must be properly fitting, well-maintained, half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for polynuclear aromatics and organic vapors. Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of creosote are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N).

> Respirators acceptable for use by applicators of pentachlorophenol must be properly fitting, well-maintained, half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors and acid gases. Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile. In addition, plastic-coated disposable coveralls impervious to dust are acceptable for dust protection.

An applicator who enters treatment cylinders and who wears protective clothing resistant to penetration by these pesticide solutions would have a significantly reduced (80%) total dermal exposure (Kozak, 1980). Although no specific risk estimate can be calculated due to the absence of exposure data in this situation, an applicator wearing a respirator would have a significantly reduced (90%) inhalation exposure, resulting in reduced risks (Kosak, 1980). When data are submitted on the permeability of protective materials when in contact with creosote formulations, the Agency will evaluate the data and will take further regulatory action if it is deemed appropriate.

Final Regulatory Position and Rationale for the Inorganic Arsenicals: The Agency received information from the wood preserving industry (AWPI, June 17, 1982) on the types of protective clothing reportedly suitable for applicator protection from the inorganic arsenicals. As a result of evaluating this information, the Agency has revised the PD 2/3 proposal to include additional detail about the types of materials for the protective clothing. This is an interim measure, however, because the Agency will, as stated above for creosote, require the registrants to submit data on the permeability of various materials used for gloves and protective clothing in contact with arsenic formulations. The registrants will be notified as to the specifics of this requirement in a separate action pursuant to FIFRA Section 3(c)(2)(B).

The Agency has also reevaluated the proposal that a respirator should be worn by applicators who enter arsenical pressure treatment cylinders. The Agency believes that the arsenic levels inside a cylinder will not exceed the background air arsenic dust levels of the plant because inorganic arsenical formulations are water-based solutions which do not typically produce vapors (USDA, 1981). Also, these formulations are applied at ambient temperatures at which vapors are not formed (PD 2/3, pp. 584 and 621).

The Agency believes, therefore, that the requirements for respiratory protection for applicators entering cylinders should be consistent with the requirements for employees in other work areas of the treatment plant; i.e., applicators entering cylinders should wear respirators if the background air arsenic dust levels are unknown or exceed 10 ug/m^3, averaged over an 8-hour period.

The Agency has concluded that in order for the benefits of pressure treatment uses of the inorganic arsenicals to exceed the risks, the labels must be modified to contain the following information:

> Applicators who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing (including overalls, jacket, gloves and boots) impervious to the wood treatment formulation.
>
> In addition, employees who enter pressure treatment cylinders must wear properly fitting, well maintained high efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10 ug/m^3), averaged over an 8-hour work period. Air monitoring programs, procedures and record retention and submission must be conducted in accordance with the instructions on the attached labeling material. Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene.

The requirement of wearing gloves during these activities will reduce the hand dermal exposure by 99% and use of coveralls will reduce the total dermal exposure by 80%, resulting in reduced risks. If the measured arsenic air level exceeds 10 ug/m^3 or is unknown and respirators become necessary, as described in the preceeding section, the risks due to inhalation exposure (assume 10 ug/m^3) will be 4.1×10^{-5} (with respirators) (Rispin, April 18, 1984). Use of respirators reduces arsenic inhalation exposure by 99%. These risk figures are based on new epidemiological and exposure data developed since the PD 2/3 was issued as discussed in Section II of this document. A comparison of the PD 2/3 risks (with and without protective measures) and recalculated risks (with protective measures) is contained in Appendix B.

3. Closed Mixing Systems for Prilled or Flaked Pentachlorophenol

Exposure/Risk: The Agency was concerned about the high inhalation and dermal exposure situations during the manual opening and emptying of bags of prilled (granular) formulations of pentachlorophenol or prilled or powder formulations of sodium pentachlorophenate in the preparation of the treatment solutions. The total oncogenic risk for this operation was estimated to range from 7.3×10^{-3} to 1.5×10^{-2} without protective clothing and equipment, and the fetotoxic MOS ranged from 6.4 to 13 (PD 2/3, p. 587). These estimates were based on 2.4 mg/m^3 airborne pentachlorophenol concentration due to bag emptying and mixing operations (PD 2/3, p. 317). The dermal exposure was assumed to be 40 to 400 mg/hr (PD 2/3, p. 319) and the rate of dermal absorption was assumed to be 1% (PD 2/3, p. 205).

PD 2/3 Proposal: To reduce the inhalation and dermal exposures during this activity, the Agency proposed in the PD 2/3:

> A closed emptying and a closed mixing system must be used for all prilled (granular) formulations of pentachlorophenol and prilled (granular) and powder formulations of sodium pentachlorophenate.

An example of an acceptable closed emptying and mixing system for handling large quantities of preservative is one in which the prilled or powder formulations are unloaded by pneumatic equipment from a hopper truck or railroad car directly into the closed (dissolving) mixing tanks. This requirement was expected to reduce the applicator exposure to pentachlorophenol and sodium pentachlorophenate to a level comparable to the background (ambient) air levels in the plant (PD 2/3, p. 628). The Agency assumed (PD 2/3, p. 561) that risks would be greatly reduced where closed systems are used for emptying and mixing activities on both a large scale and small scale (emptying bags).

The Agency's final regulatory position regarding closed systems for pentachlorophenol is discussed in the paragraphs which follow. The position for sodium pentachlorophenate, a non-pressure use, is the same and is presented in Section VI. F of this PD 4.

Final Regulatory Position and Rationale: The SAP recommended that the Agency investigate ways to reduce exposure to the dry formulations of pentachlorophenol and sodium pentachlorophenate other than by imposing the requirement of closed systems because "...such a requirement would impose an unfair burden on small operators in terms of additional capital investment."

AWPI (#36:30000/28C) commented that the Agency had overestimated the time spent opening and emptying bags of prilled and flaked pentachlorophenol and mixing pentachlorophenol solutions, as discussed in Section II of this document. After evaluating this submission, the Agency revised the PD 2/3 exposure analysis from an estimate of 4 hours/day for 5 days/week to a maximum of 2 hours/day for 2 days/week for bag emptying and mixing.

In light of the SAP recommendation and reduced time of exposure resulting in a lower risk to applicators, the Agency reevaluated the PD 2/3 proposal regarding the mandatory use of closed systems for dry pentachlorophenol and sodium pentachlorophenate formulations.

If closed systems are used, exposure will be reduced to ambient levels at 0.028 mg/m^3 based on Arsenault (1976) and thus risks would be significantly decreased. For general operations in a treatment plant, the exposure to pentachlorophenol at ambient levels is 4.1 ug/kg/day (Rispin, April 18, 1984). The Margin of Safety for teratogenic/fetotoxic effects is 730 (Rispin, April 18,1984). The oncogenic risk due to inhalation exposure is estimated to be negligible because of the low vapor pressure of HxCDD at 6.6×10^{-7} mm Hg (U.S.E.P.A Science Advisory Board, 1978).

The cost of installing closed systems for bag emptying would be approximately $10,000. If closed systems are not used, the alternative of wearing gloves and coveralls during the emptying of bags prilled or flaked pentachlorophenol would reduce total dermal exposure by 80% and a respirator would reduce inhalation exposure by 90%. If this protective clothing and equipment are used, the total oncogenic risks range from 4.3×10^{-4} to 4.3×10^{-5} and the fetotoxic MOS ranges from 400 to 160 (Rispin, April 18, 1984). The recalculated inhalation risk estimates were based on an airborne pentachlorophenol concentration of 2.4 mg/m^3, the highest level that can be tolerated by persons conditioned to exposure (PD 2/3, p. 317). Pentachlorophenol concentrations higher than 2.4 mg/m^3 cause severe respiratory distress (PD 2/3 p. 317).

The recalculated dermal risk estimates were based on the dermal exposure of the insecticide Guthion in powdered form (40 mg/hr) and the fertilizer disulfoton as a dry mix (400 mg/hr) (Rispin, April 18, 1984). The risks were not based on actual prilled/flaked pentachlorophenol exposure data. Pentachlorophenol manufacturers are presently producing "glazed-flaked" forms of dry pentachlorophenol in an effort to reduce the amount of small particulates that may become airborne (AWPI, Aug. 18, 1982). Therefore, the actual dermal and inhalation exposure for current dry pentachlorophenol products is likely to be somewhat less, and the risks to applicators due to exposure to dry pentachlorophenol when emptying and mixing bags are also likely to be somewhat lower than those stated above (Day, Jan. 31, 1984). The current dermal absorption assumptions for dry pentachlorophenol are the same as those of the PD 2/3, except that the HxCDD dermal absorption rate is assumed to be 50% based on data from a dermal absorption study in rats using TCDD by Poiger and Schlatter (1980) (Rispin, April 24, 1984).

While oncogenic risks may be somewhat lower than the stated range of 4.3×10^{-4} to 4.3×10^{-5}, the Agency has no exposure data to determine how much lower. Therefore, because closed systems are expected to significantly reduce exposure to pentachlorophenol, the Agency has determined that closed systems must be used when emptying and mixing bags of prilled or flaked pentachlorophenol for pressure treatment uses. Because the Agency realizes this may present a financial hardship to the smaller wood treatment operators, the Agency will require that the closed systems be "phased in" over a period of 3 years. This will enable the smaller operators to plan for the financial investment.

During the three-year period before closed systems are in place, the Agency has concluded that respirators and protective clothing must be worn, if closed systems are not in place, in order to protect applicators while empyting and mixing bags of prilled or flaked pentachlorophenol.

Therefore the Agency will require that 30 days after publication of the Notice concluding the Wood Preservaties RPAR in the Federal Register or 30 days after receipt of the Notice by the registrant, whichever occurs later, registrants must file an amended application to include the following information on labels of prilled or flaked pentachlorophenol formulations:

> Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls) must be worn when emptying and mixing prilled or flaked formulations of pentachlorophenol. After September 1, 1987, a closed system must be used when emptying and mixing prilled or flaked formulations of pentachlorophenol. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

Respirators acceptable for use by applicators of pentachlorophenol and examples of acceptable materials for gloves required during application and handling of pentachlorophenol are described in Section VI.C.5 of this document. This information must also be included on the labels.

The same label statements will be required for prilled and flaked pentachlorophenol for millwork and plywood use (Section VI.H) and for powdered sodium pentachlorophenate (Section VI.G). This protective measure will reduce pentachlorophenol exposure to 0.024 mg/m^3, the concentration in ambient air at treatment plants (Arsenault, 1976). The potential inhalation oncogenic risk will then be negligible and the MOS for teratogenic/fetotoxic effects will be 730 (Rispin, April 18, 1984).

4. No Visible Surface Deposits for Arsenicals

Exposure/Risk: Workers in treatment plants that apply inorganic arsenical formulations are exposed to the background (ambient) arsenic dust via inhalation exposure. This dust results from the leaching, drying and subsequent flaking off of the inorganic arsenical formulations from the surface of the treated wood which is drying in the yards. The contribution this dust makes to the ambient levels of arsenic is related to the levels of surface residues of the inorganic arsenic formulations.

Treatment plant applicators are also exposed to residues of arsenic via handling of dry treated wood. Thus, the Agency was concerned that treatment plant applicators, as well as end-users of arsenical-treated wood, were exposed to arsenic through ambient air levels and through dermal contact with the surface residues.

PD 2/3 Proposal: To reduce this source of inhalation and dermal exposure to the treatment plant applicators, the Agency proposed in the PD 2/3 the requirement that:

> The inorganic arsenical treatment solutions must be filtered prior to use in the treatment cylinders and an additional vacuum step must be used prior to the removal of the treated wood from the treatment cylinders. In addition to these requirements, recommended control technologies to reduce the surface levels of arsenic on the treated wood include the use of wood that is free of heavy resins ("clean" wood), the post-treatment rinsing of the treated wood, and the installation of protective sheds or covers over the drying treated wood.

Reducing surface residues of arsenic on the treated wood was expected to reduce the inhalation and dermal exposure to the end-users of the treated wood. Although the reduction in arsenic residues achieved by the use of the technologies proposed in the PD 2/3 could not be accurately quantified until a standardized sampling method became available, the Agency believed that significant reduction in residues would result from implementation of these specific technology measures during the application process, and hence a significant reduction in risks.

Final Regulatory Position and Rationale: AWPI (February 9, 1982) stated that there are industrial methods currently used to reduce surface residues of arsenic on treated wood and that these methods include several process control technologies available to the wood treater. The effective use of any one or more of these steps to reduce surface residues depends upon a number of variables including the season and climate, size of the plant, type of wood, and the solution being used. The various technologies include controls on the wood used, maintenance of clean facilities, draining excess solutions from the wood after treatment, filtering solutions, improving the purity of treating solutions, pH control of treatment solutions, an additional vacuum step in the treatment process, post-treatment washing of treated wood, and varying drying processes. AWPI also stated that steps which effectively reduce surface residues under one set of conditions will not yield similar results under different conditions and that judgments as to which steps are necessary to reduce surface residues should be left to the individual applicators.

USDA (1981) also stated in its comments to the Agency that industry should be allowed to meet a clean-wood standard in ways that best suit their specific situations.

The Agency has evaluated the industry standards and methods of achieving clean wood and has determined that surface residues of arsenic will be effectively reduced if the labels are modified to include the following information:

> Processes used to apply inorganic arsenical formulations shall leave no visible surface deposits, as defined by AWPA Standard C-1 and AWPB Standards LP2 and LP22. Visible surface deposits mean a surface residue or crystallization on the treated wood. Small isolated or infrequent spots of chemical on otherwise clean wood may be allowed.

The Agency has concluded that this requirement will reduce surface residues of arsenic on the treated wood and will significantly reduce the inhalation and dermal exposure and resultant risk to an applicator and to end-users of treated wood. This requirement will allow the applicator the choice of several treatment technologies to reduce the surface residues of arsenic on the treated wood.

5. Use of Protective Gloves

Exposure/Risk: The Agency expressed concern in the PD 2/3 that the treatment plant applicators may be dermally exposed to the wood treatment solutions when mixing the wood preservatives and when cleaning and maintaining treatment equipment, such as pressure cylinders (all three chemicals) and vats (pentachlorophenol or sodium pentachlorophenate). Applicators may also be exposed to the treatment solutions when handling freshly treated lumber, when emptying and mixing bags of powder formulations, or when applying the preservative solution.

Due to insufficient data, the Agency was unable to quantify the dermal exposure from hand contact for 1) all activities in which contact with creosote solution is likely to occur, 2) activities such as entering cylinders and opening cylinder doors in which dermal contact with the inorganic arsenicals solution is likely to occur, and 3) those activities such as opening cylinder doors, cleaning of equipment, and handling pentachlorophenol-treated wood in which dermal contact with the pentachlorophenol solutions is likely to occur.

The Agency, however, was able to estimate the total inorganic arsenical exposure while handling wet freshly treated wood and diluted solutions. The total oncogenic risk, without gloves, was 2.6 x 10^{-2} (PD 2/3, p. 217) and the teratogenic/fetotoxic Margin of Safety (MOS) was 417 (PD 2/3, p. 245). The risk estimate for arsenic also includes the inhalation exposure due to the treatment plant (background) arsenic levels.

PD 2/3 Proposal: To reduce risks the Agency proposed the following requirement:

> All applicators wear gloves impervious to the wood treatment solution (e.g., rubber) in all situations where dermal contact with creosote, pentachlorophenol, or the inorganic arsenicals is possible (e.g., handling treated wood and opening cylinder doors).

Although adequate experimental data were not available on the permeability of gloves to these wood preservatives, the Agency estimated (PD 2/3, p. 556) that an applicator wearing gloves resistant to penetration by these wood preservatives would have significantly reduced (by 99%) exposures to these pesticides via the hands alone. The reduction in total dermal exposure is about 30%.

As stated in the PD 2/3 (p. 615), wearing gloves while handling freshly-treated inorganic arsenical-treated wood and diluted solutions results in a reduction of total (dermal and inhalation) oncogenic risk from 2.6 x 10^{-2} (without gloves) to 1.91 x 10^{-2} (with gloves) and a teratogenic/fetotoxic Margin of Safety (MOS) increase from 417 to 499. Although the total inorganic arsenical risk has not been significantly reduced in this situation due to the inclusion of the risk from inhalation exposure, the dermal exposure to the inorganic arsenicals via the hands is significantly reduced (by 99%). The risk probability of skin cancer to an individual would be reduced from 7.0 x 10^{-3} to 1.0 x 10^{-4} by wearing gloves for this activity (PD 2/3, p. 615).

Final Regulatory Position and Rationale: Based on rebuttal comments (AWPI #36:30000/28C) to the PD 2/3, the Agency revised some of the inorganic arsenical exposure assumptions for inhalation as discussed in Section II of this document. The estimate of airborne arsenic in a treatment plant environment has been lowered to 0.01 mg/m^3 from 0.07 mg/m^3. In the absence of inhalation absorption data for arsenic laden dust in the ambient air of treatment plants, the Agency assumes 100% inhalation absorption as in the PD 2/3.

The recalculated inhalation oncogenic risk to applicators handling freshly treated wood in inorganic arsenical treatment plants would be 4.1 x 10^{-5} (assume 10 ug/m^3) if respirators are worn (Rispin, April 18, 1984). The recalculated dermal risk is 6.2 x 10^{-4} with gloves, assuming 90% protection (Rispin, April 18, 1984).

The Agency also received information on the types of materials appropriate for protective clothing to reduce exposure to the various wood preservative formulations (AWPI, June 17, 1982), but, as described previously in Section

VI.C.2 of this PD 4, will require registrants to provide permeability data for various glove materials in contact with arsenic and creosote formulations. The Agency will revise the assumption of 90% protection by gloves if the data indicate otherwise.

The Agency has revised the PD 2/3 proposal and has determined that, in order for the benefits to exceed the risks for pressure treatment uses of all three wood preservatives, the following information must appear on the wood preservative labels:

> Applicators must wear gloves impervious to the wood treatment formulation [e.g., inorganic arsenicals: vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene; creosote: polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N); pentachlorophenol: polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile] in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors).

The Agency has revised the language of this requirement ("wearing gloves where dermal contact is expected" rather than "where dermal contact is possible") because the word "expected" provides clearer guidance to the applicator. The word "possible" is overly broad and does not limit the requirement to the situation of concern.

6. Disposal of Protective Clothing and Pesticide Formulation

Exposure/Risk: The Agency expressed concern in the PD 2/3 that, although not quantified, there are potential risks from creosote, the inorganic arsenicals and pentachlorophenol containing pesticide-laden dust or treatment solutions which adhere to protective clothing and workshoes and are transported from the treatment plant into the home. This practice of bringing contaminated protective clothing and workshoes into the home creates a potential exposure to the workers' families. The Agency sought to eliminate or greatly reduce this potential source of wood preservative exposure in treatment plant workers' homes.

PD 2/3 Proposal: The PD 2/3 proposal for a label modification to reduce this type of exposure was:

> All applicators must leave all protective clothing, workshoes or boots, and equipment at the plant at the end of the day. Worn-out protective clothing must be disposed of in accordance with the instructions for pesticide container disposal.

Final Regulatory Position and Rationale: The PD 2/3 proposal stated that disposal of worn-out protective clothing be in accordance with the instructions on the label for pesticide container disposal. The direction on the labels of the wood preservatives regarding disposal of the containers states that the containers should be triple-rinsed prior to disposal according to Subtitle C of the Resource Conservation and Recovery Act (RCRA).

The Agency did not intend by the PD 2/3 proposal that protective clothing be triple-rinsed prior to disposal and therefore has revised the wording of the statement for clarification. The revised language describes exactly how the worn-out protective clothing and worn-out workshoes or boots must be disposed of.

The International Woodworkers of America (68:30000/28C) commented that the PD 2/3 proposal was not clear about the cleaning of protective clothing and were concerned that applicators might come into contact with the pesticides from their contaminated protective clothing. Based on this comment, the Agency has concluded that there should be a statement on the label indicating that there should be a change of protective clothing when such clothing shows signs of contamination. This label language was also recommended in a NIOSH report (1983).

The Agency has determined that registrants must revise their pressure-treatment pesticide labels for products containing inorganic arsenicals to include the following information:

> Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing, workshoes or boots, and equipment at the plant. Worn-out protective clothing and work shoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with State and Federal regulations.

For products containing creosote or pentachlorophenol for pressure treatment, labels must be modified to include the following information:

> Protective clothing must be changed when its shows signs of contamination. Applicators must leave protective clothing, workshoes or boots, and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a general landfill, in the trash, or in any other manner approved for pesticide disposal.

The Agency has adopted the revised requirement because it reduces potential exposure to the workers' families from these wood preservatives and because it is more specific regarding the method of disposal than the PD 2/3 proposal. The new language clarifies the Agency's intention regarding disposal of protective clothing includes "work shoes or boots" which, when worn-out, must be disposed of as well as protective clothing, and is more specific about the sites for disposal than the PD 2/3 proposal for pentachlorophenol and creosote. Protective clothing contaminated with the inorganic arsenicals may be a hazardous waste as defined by 40 CFR 261.24 under the Resource Conservation and Recovery Act (RCRA) if an extract from the waste contains arsenic at a concentration equal to or greater than 5.0 milligrams per liter. Therefore, protective clothing contaminated with the inorganic arsenicals must be disposed of appropriately in accordance with State and Federal regulations.

On March 29, 1983, the Agency notified all manufacturers, formulators and registrants of pesticides that the labels for all pesticide products must include updated storage and disposal statements (U.S. EPA, PR Notice 83-3, March 29, 1983). The Notice indicated that, for arsenic formulations, labels must bear the following pesticide disposal statement:

> Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Although not all wastes containing arsenical compounds are listed under RCRA as acute hazardous wastes, the inorganic arsenicals used as wood preservatives are listed as acute hazardous wastes under 40 CFR 261.33(e).

The Notice (PR 83-3) indicated that, for pentachlorophenol and creosote products, except those intended solely for household use, the labels must bear the following pesticide disposal statement:

> Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

In addition to other label amendments required in this PD 4, the Agency has concluded that labels of wood preservative formulations must be amended as stated in PR Notice 83-3 regarding disposal of unused or spent formulations containing pentachlorophenol, creosote, or inorganic arsenicals.

7. Warnings Regarding Eating, etc., during Application

Exposure/Risk: It is not unusual for treatment plant workers to eat their lunches and smoke in the yard around stacks of treated wood or when handling freshly treated wood, thus creating a potential for accidental ingestion through contamination of food, drinks, and inhalation during smoking. Although the risks of accidental contamination of food, drink, or tobacco products with wood preservatives through oral exposure have not been quantified, the Agency believes there is a potential risk from these activities.

PD 2/3 Proposal: The Agency proposed in the PD 2/3 the following label modification:

> Eating, drinking and smoking are prohibited during the application of creosote, pentachlorophenol, and the inorganic arsenical wood preservative pesticides by pressure treatment.

The Agency proposed the stated prohibitions in order to achieve a reduction in the applicator's oral exposure.

Final Regulatory Position and Rationale: The Agency has concluded that the following information must be included on the labels for pressure-treatment uses of pentachlorophenol, creosote, and the inorganic arsenicals:

> Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation (e.g., manually opening/closing cylinder doors, moving trams out of cylinders, mixing chemicals and handling freshly treated wood). Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

The Agency has revised the PD 2/3 proposal because the revised version broadens the scope of prohibiting the use of all tobacco products (e.g., chewing tobacco) in the treatment area. It also further defines the specific exposure situations when eating, drinking, and smoking should be prohibited and thus provides clearer guidance to the applicator than the PD 2/3 recommendation. This label instruction will accomplish the Agency's goal of reducing accidental exposure to applicators via eating, drinking, and smoking. The final requirement is also more specific than the PD 2/3 proposal in that it requires washing after skin contact.

8. Risk Reduction Measures Regarding Opening Treatment Cylinder Doors

Exposure/Risk: During a brief time (about 1 hour per day), an applicator may be manually opening cylinder doors following the pressure treatment of wood. While the cylinder door is being opened, it is possible to dermally contact the treatment solutions that have splashed and dried around the cylinder door. In addition, immediately after the door is opened, hooks are manually attached to the charge of wood for its removal from the cylinder. During this operation the applicator may dermally contact the treatment solutions.

The Agency was concerned that treatment plant applicators may be more extensively and significantly exposed (dermal and inhalation) to creosote and pentachlorophenol solutions and vapors while performing this particular activity than during other activities around and about the treatment plant.

In the case of creosote, although the Agency has no quantitative data demonstrating that workers involved in the opening of cylinder doors following treatment are exposed to higher levels of the pesticide than in other work situations, it seems reasonable to assume that in this particular situation a greater exposure could occur.

For pentachlorophenol, the Agency has data on the applicator's inhalation exposure only, but lacks information on the dermal exposure occuring during the opening of cylinder doors. The oncogenic risk resulting from inhalation alone under these circumstances was estimated to be 6.4 x 10^{-4}; the MOS for fetotoxic effects is estimated to be 150 in this situation (PD 2/3, pp. 587, 588).

Because inorganic arsenical formulations are water-based solutions which do not typically produce vapors, the Agency determined that the air arsenic concentrations while opening the cylinder door following treatment will not exceed the background air arsenic dust levels of the plant (PD 2/3, p. 584). Thus, the inhalation exposure would not be higher than that of any other applicator activity.

PD 2/3 Proposal: In the PD 2/3, the Agency proposed requiring that all applicators who open pentachlorophenol or creosote treatment cylinder doors wear gloves and a properly maintained half-mask canister or cartridge respirator designed for that pesticide's use. An applicator wearing gloves resistant to penetration by these pesticide solutions would have a signifiqantly reduced hand dermal (by 99%) (Kosak, 1980) exposure. An applicator wearing a respirator while performing this activity with creosote or pentachlorophenol will have a significantly reduced inhalation exposure (by 90%), resulting in significantly reduced risks.

For pentachlorophenol the oncogenic risk would be decreased from 6.4×10^{-4} to 6.4×10^{-5} and the fetotoxic MOS would be increased from 150 to 1,500 if these protective measures were taken (PD 2/3, pp. 657, 661).

As discussed in Section VI.C.5 of this document, the PD 2/3 proposed that gloves be worn by arsenic applicators when opening clyinder doors. As discussed in Section VI.C.1 of this document, the PD 2/3 proposed that all workers in arsenical treatment plants must wear dust masks.

Final Regulatory Position and Rationale: The Agency has concluded that the following information must be included on the label for pressure treatment uses of pentachlorophenol and creosote:

> Pressure-treatment pentachlorophenol and creosote applicators who manually open cylinder doors must wear gloves and a respirator.

The types of gloves and respirators acceptable for creosote and pentachlorophenol which must be included on the label were described previously in Section VI.C.2 of this document. As discussed in Section II of this document, this requirement will also reduce hand dermal exposure by 90% (Rispin, April 18, 1984) and inhalation exposure by 90% to these wood preservatives, but is more specific than the PD 2/3 about the type of respirator and materials appropriate for gloves.

The oncogenic risk due to exposure to pentachlorophenol was recalculated using the multi-stage model, as discussed in Section II of this document. An applicator wearing a respirator while opening cylinder doors would have an inhalation oncogenic risk of 3.1×10^{-6} and a fetotoxic MOS of 1,500 as compared with 6.4×10^{-5} and 1,500, respectively, calculated for the PD 2/3 proposal.

9. Restricted Use

Exposure/Risk: The Agency was concerned that the risk of human exposure would be higher if untrained or unsupervised applicators used any of the three wood preservatives as compared with trained applicators. By preventing untrained or unsupervised applicators from using these pesticides, the risk of human exposure due to misuse or carelessness would be significantly reduced.

PD 2/3 Proposal: The Agency proposed in the PD 2/3 to classify pressure treatment uses of the three wood preservatives for "Restricted Use" only. Under FIFRA, hazardous pesticides may be classified for restricted use and be limited to use only by or under the direct supervision of certified applicators. To become certified, the applicators must enroll in a certification program, which teaches the safe use and disposal of restricted use pesticides. Upon completion of these programs, the applicators are certified for a particular restricted use pesticide or pesticides. Therefore, the Agency proposed the following label modification for pressure treatment uses of all three wood preservatives:

> Restricted for sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

Final Agency Position and Rationale: The Agency has adopted the PD 2/3 proposal as the final regulatory position because it will assure that applicators will be properly trained in the safe handling of the three wood preservatives. The Agency has concluded that labels for pressure-treatment uses of pentachlorophenol, creosote, and the inorganic arsenicals must be modified to include the following information:

> Restricted Use Pesticide: Restricted for sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

The Agency believes that this restriction will reduce the opportunity for misuse of the pesticides and will therefore decrease exposure and potential risks to applicators and is, therefore, necessary to prevent unreasonable adverse effects.

10. Closed System/Arsenical Powders

Exposure/Risk: The PD 2/3 assummed that treatment plant workers who empty bags containing inorganic arsenical powder formulations in the preparation of the treatment solutions contact up to 10 grams of arsenic dust via the skin. The amount of inhaled arsenic dust is also increased over background levels as a result of this activity. The Agency assumed in the PD 2/3 that all ambient dust resulting from bag emptying will be respirable and will reach the lungs, rather than the gastrointestinal tract, due to the small particle size. The Agency estimated that a total lifetime oncogenic risk of 3.4×10^{-2} and a teratogenic/fetotoxic MOS of 294 would result from bag emptying of inorganic arsenical powder formulations (PD 2/3, p. 582).

PD 2/3 Proposal: The Agency proposed in the PD 2/3 to require closed systems for the emptying and mixing of powder formulations of the inorganic arsenicals to reduce inhalation and dermal exposures during this activity. An example of an acceptable closed emptying and mixing system was described previously in Section VI.C.3 of this document. This requirement was expected to reduce the applicator exposure to the inorganic arsenicals to a level that is comparable to the background (ambient) air levels in the plant. The Agency assumed dermal exposure is negligible where closed systems are used for emptying/mixing activities.

Final Agency Position and Rationale: As discussed in Section II of this document, the Agency based the recalculated dermal exposure estimate on monitoring data obtained with Guthion powder and dry mix fertilizer. The Agency estimated a dermal exposure of 3.8 to 142 mg/hr and 0.1% absorption or 0.0038 to 0.142 mg/hr while dumping bags of FCAP for 1 hour/day for 5 days/week for 240 days/year over a working lifetime.

For inhalation exposure, the Agency assumed an upper limit of 10 ug/m^3, because if it were higher respirators would be required and inhalation exposure would be reduced by 99% as previously discussed (Section VI.C.1). The recalculated dermal risk for opening bags of FCAP is 7.3×10^{-3} without protective measures; the recalculated inhalation risk is 4.1×10^{-3}, assuming 10 ug/m^3 exposure to arsenic (Rispin, April 18, 1984).

Since the PD 2/3 was published there were no comments received from the public disagreeing with the PD 2/3 proposal to require closed systems for emptying and mixing powdered forms of the inorganic arsenicals. It is the Agency's understanding that closed systems are already being used in the workplace for this exposure situation. Therefore, in light of the potential risk to applicators and lack of additional data/comments from the public to alter the position presented in the PD 2/3, the Agency has concluded that labels for powder formulations of the inorganic arsenicals must be modified to include the following information:

> A closed emptying and mixing system must be used for all powder formulations of the inorganic arsenicals. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

This requirement is identical to the Agency's proposal in the PD 2/3 and will significantly reduce exposure to the powdered inorganic arsenicals to levels which are not above ambient air levels in the plant. It is assumed that closed systems result in minimal exposure.

D. Poles-Groundline Uses: Pentachlorophenol and Creosote

Sections VI.D through VI.H of this document discuss non-pressure treatment uses of the three wood preservatives.

This section (VI.D) discusses uses of creosote and pentachlorophenol which are for wood preservative treatment of utility poles (e.g., telephone or electrical) 6 inches above and 16 inches below the groundline (poles-groundline).

1. Use of Protective Gloves

Exposure/Risk: Creosote poses potential oncogenic and mutagenic risks to humans, however this risk has not been quantified for the poles-groundline use. There are very little data available regarding workers' exposure to all of the specific oncogenic or mutagenic components of creosote. However, there are many reports of incidences of skin cancer among wood treaters and other workers who apply creosote.

Dermal exposure to the workers who apply pentachlorophenol for poles-groundline use occurs during the handling and application of the wet paste. The Agency believes this exposure will occur primarily through the hands. Due to the nature of the operation, however, some splattering of treatment solution onto other areas of exposed skin may also occur.

PD 2/3 Proposal: To reduce the risk caused by dermal exposure, the Agency proposed in the PD 2/3 that all applicators using pentachlorophenol and/or creosote for poles-groundline uses wear gloves impervious to these pesticides. The wearing of gloves was expected to reduce the dermal exposure from hand contact with these chemicals (pentachlorophenol and/or creosote) by 99%. Specifically, the PD 2/3 proposed:

> All applicators must wear gloves impervious to the creosote and pentachlorophenol poles-groundline formulations (e.g., rubber) in all situations where dermal contact with pentachlorophenol and/or creosote is possible.

Final Agency Position and Rationale: The Agency has concluded that labels for pentachlorophenol and/or creosote formulations for poles-groundline use must contain the following information:

> Applicators must wear gloves impervious to the wood treatment formulation (e.g., polyvinyl acetate, polyvinyl chloride or neoprene) in all situations where dermal contact is expected (e.g., during the actual application process and when handling freshly treated wood).

The differences between the PD 2/3 proposal and the final requirement are: a change from "wearing gloves where contact is possible" to "wearing gloves where contact is expected" (for rationale, see Section VI.C.5 of this document); the description of the types of gloves which are appropriate (AWPI, June 17, 1982, and Silkowski, 1982); and addition of the exposure situation of "during the actual application process" for clarification. As indicated in Section VI.C.2 and VI.C.5, the Agency will require registrants to provide permeability data for contact of various protective materials with creosote formulations.

The Agency has adopted this requirement because it provides for the reduction in dermal exposure from hand contact (by 90%), with clearer guidance to the applicator.

2. Use of Coveralls

Exposure/Risk: It is likely, during the treatment of poles at groundline with creosote and/or pentachlorophenol, that some spillage or splattering may occur on the arms and legs as well as the hands. The Agency proposed in the PD 2/3 to require that applicators of creosote and/or pentachlorophenol wear other protective clothing, such as disposable coveralls, to reduce risks to a greater degree than the risk reduction resulting from gloves alone. The Agency, however, did not quantify the extent to which exposure would be reduced.

PD 2/3 Proposal: The PD 2/3 proposal stated:

> All applicators must wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing during the application process.

Final Agency Position and Rationale: The Agency has determined that the labels for pentachlorophenol and/or creosote formulations for poles-groundline use must be modified to include the following information:

> Applicators must wear disposable coveralls (e.g., for creosote: nitrile or neoprene; for pentachlorophenol: nitrile or polyethylene) or other suitable impermeable protective clothing during the application and mixing processes in all situations where dermal contact is expected.

The changes from the PD 2/3 proposal are a clarification of the acceptable materials for the coveralls (AWPI, June 17, 1982), and a clarification of the exposure situation from "during the application process" (PD 2/3) to "application and mixing processes in all situations where dermal contact is expected."

These requirements will reduce the applicator's total dermal exposure from the splattering of the pesticide during the application process. Additional data on permeability of recommended materials, however, are required as discussed in Section VI.C.2 of this PD 4.

3. Disposal of Protective Clothing and Pesticide Formulations

Exposure/Risk: Although not quantified by the Agency, there are potential risks resulting from pentachlorophenol and/or creosote adhering to clothing and shoes and not being disposed of properly.

PD 2/3 Proposal: To reduce risks from this potential exposure, the Agency proposed in the PD 2/3 that:

> All applicators must dispose of worn-out protective clothing in accordance with the instructions for pesticide container disposal.

Final Regulatory Position and Rationale: The Agency has determined that the following information must be included on the labels for the poles-groundline uses of pentachlorophenol and/or creosote formulations:

> Protective clothing must be changed when it shows signs of contamination. Launder non-disposable protective clothing separately from other household clothing. Dispose of worn-out protective clothing and workshoes or boots in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

As previously explained in Section VI.C.6 of this document, this label modification clarifies the Agency's intent regarding proper disposal, so that the requirements for container disposal, which included three rinses, are not imposed. It includes the disposal of worn-out "workshoes or boots" and is more specific about where disposal may take place than the PD 2/3 proposal. Also, instructions are provided regarding changing protective clothing and laundering any non-disposable protective clothing belonging to the applicator.

The final requirement also accomplishes the reduction of exposure to the workers' families from these wood preservatives and clarifies the Agency's intention about disposal procedures and sites.

As explained in Section VI.C.6 of this PD 4, The Agency will also require that labels of poles-groundline formulations containing creosote and pentachlorophenol be amended to include the following information as stated in PR Notice 83-3 (U.S. EPA, March 29, 1983):

> Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

4. Warnings about Eating, etc., During Application

Exposure/Risk: Although the risks due to accidental ingestion of wood preservatives by smoking, drinking, or eating during poles-groundline treatment have not been quantified, the Agency has determined (PD 2/3) that there is potential for adverse human health effects in these use situations.

PD 2/3 Proposal: To eliminate risks from this potential exposure, the Agency proposed the following prohibition:

> Eating, drinking and smoking is prohibited during the application of creosote and pentachlorophenol products for the poles-groundline use.

Final Regulatory Position and Rationale: As previously described for pressure treatment uses of the wood preservatives (Section VI.C.7), the Agency has determined that the labels for poles-groundline uses of pentachlorophenol and/or creosote formulations must be modified to include the following information:

> Applicators must not eat, drink, or use tobacco products during those parts of the application process which may directly expose them to the wood treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products or using restrooms.

This label language will greatly reduce the applicator's exposure during the application process. The rationale for revising the PD 2/3 proposal regarding this issue has been discussed previously in this document in Section VI.C.7. To summarize, it broadens the scope of prohibiting the use of all tobacco products (e.g., chewing tobacco), further defines the exposure situations of concern, and requires washing after skin contact. The requirement also satifies the Agency's concerns because it reduces the potential for accidental exposure during the application of these wood preservatives.

5. Restricted Use

Exposure Risk: The Agency was concerned about the possibility of the high risk of exposure to applicators who had not been properly trained in the safe handling and disposal of the poles/groundline formulations of pentachlorophenol and/or creosote.

PD 2/3 Proposal: In order to reduce the probability of exposure due to misuse or carelessness as discussed previously for pressure treatment uses of wood preservatives, the Agency proposed in the PD 2/3 the following label amendment for poles-groundline formulations of pentachlorophenol and/or creosote:

> Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

Final Agency Position and Rationale: The Agency has determined that poles-groundline formulations of pentachlorophenol and/or creosote must contain the following label information:

> Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

This requirement is the same as that proposed in the PD 2/3 and will assure that applicators will be properly trained in the safe handling of these formulations. Thus, risk of exposure will be reduced.

E. Home and Farm Uses (Including Railroad Tie Repair)--Pentachlorophenol and Creosote

This Section presents this Agency's position for "home and farm" uses of pentachlorophenol and creosote products which may be applied by non-pressure methods, for example, by brushing, dipping, or spraying the wood. The "home and farm" uses also include applications by railroad workers to preserve railroad ties; therefore all the requirements stated in this Section will apply to products used for non-pressure applications by railroad workers also.

1. Creosote: Restricted Use

Exposure/Risk: The Agency is concerned about the possibility of high exposure to home and farm applicators who have not been properly trained in the safe handling procedures for formulations of creosote products which could be obtained "over-the-counter." The Agency is concerned about the potential for high exposure to products requiring spraying and to products requiring mixing and/or diluting where there could be some splashing of the formulation resulting in dermal and inhalation exposure.

PD 2/3/Proposal: To protect the home and farm applicator from these potentially high exposures to creosote products, the Agency proposed the following in the PD 2/3.

> Restricted Use Pesticides: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

Final Regulatory Position and Rationale:

For home and farm use creosote products, including those products for railroad tie repair, the Agency will require that the labels be modified to include the following information:

> Restricted Use Pesticide: For sale to and use only by certified applicators or by personnel under their direct supervision and only for those uses covered by the certified applicator's certification.

Although the SAP recommended that the Agency find ways of enabling farmers with small farming operations to use creosote without becoming certified, the Agency continues to be concerned about the potential risk of oncogenicity and mutagenicity for 3 to 6 million home and farm users applying 2.0 million pounds of creosote [46 FR 13020]. Registered alternatives which are available include copper naphthenate, copper-8-quinolinolate, zinc napthenate and tributyltin oxide, though there may be various drawbacks for certain use situations. Other alternative measures include untreated wood, non-wood materials (e.g., aluminium and concrete), pressure-treated wood, or a naturally resistant wood species, though the latter are in short supply. In light of the Agency's continued concern about risk and because of the availability of alternative chemicals or materials, the Agency has determined that restricting the use of creosote products is necessary to significantly reduce exposure due to misuse or carelessness by an applicator not properly trained in safe handling procedures. Although this change in classification of creosote for the home and farm use may increase the burden of using these products, the Agency has determined that the burden is outweighed by the benefits of assuring that these products are used only by applicators adequately trained to use them. Other protective measures described below in this Section include use of protective gloves, protective clothing, proper instructions for disposal of protective clothing, and warnings about eating during applications.

2. Pentachlorophenol: Restricted Use

Exposure/Risk: As with creosote, the Agency was concerned about the potentially high exposure to home and farm applicators, including those repairing railroad ties with pentachlorophenol, from use of pentachlorophenol products. In particular the Agency was concerned about those pentachlorophenol products requiring spraying, and products having a pentachlorophenol concentration greater than 5%.

PD 2/3 Proposal: In order to reduce the risks due to these exposures, the Agency proposed the following in the PD 2/3 for home and farm products containing a pentachlorophenol concentration greater than 5%:

> Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

The Agency also proposed the cancellation and denial of registration of the spray method of application of pentachloropnenol products which are available for retail sale in concentrations of 5% or less.

Final Regulatory Position and Rationale:

As with creosote, the Agency continues to be concerned about exposure to applicators who apply, mix or dilute pentachlorophenol products, because of the exposure inherent in the application process and because there could be some accidental splashing of the formulation resulting in dermal and inhalation exposure. As described in Section II of this PD 4, there has been an increase in the estimated rate of dermal absorption for pentachlorophenol from 10% (PD 2/3) to 50%, and a decrease in the estimated amount of protection afforded by gloves from 99% (PD 2/3) to 90%. This has resulted in a decrease in the estimated margins of safety for teratogenic effects from 560 (PD 2/3) to 12, assuming the applicator wears gloves. The Agency is concerned that the Margin of Safety for fetotoxic effects is 12 and has determined that the risks to untrained applicators from exposure to pentachlorophenol by brushing on 5% pentachlorophenol formulations are not outweighed by the benefits unless the applicator is educated in safe handling procedures in a certification program.

Regarding the proposed cancellation of registrations of pentachlorophenol spray products in concentrations of less than 5% pentachlorophenol, the Agency now realizes that if certified applicators wished to spray pentachlrophenol concentrations at less than 5%, they would have to buy a more concentrated formulation, mix it and dilute it. Because this adds another possible source of exposure, the Agency will not cancel registrations of the pentachlorophenol spray products of less than 5% pentachlorophenol. The Agency will require that applicators be certified to use all pentachlorophenol spray products.

Thus, all labels of pentachlorophenol home and farm products, including those pentachlorophenol products for railroad tie repair, must be modified to contain the following information:

> Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their

direct supervision and only for those uses covered by the certified applicator's certification.

As described above for creosote formulations, applicators who repair railroad ties using pentachlorophenol formulations also should be trained in the proper handling of wood preservatives, even for situations where the application is automated. Thus applicators must be certified or work under the direct supervision of a certified applicator. In addition, because of concerns about the low Margin of Safety of 12 for fetotoxic effects, the Agency will require that certified applicators must wear certain protective clothing and/or equipment as described below in this section. For application of pentachlorophenol by a spray method, these protective measures include gloves, protective clothing, head covering, respirators and eye protection. For the other methods of application of pentachlorophenol products (e.g., brushing), the protective measures include gloves and disposable coveralls or other suitable impermeable protective clothing. The exposure and risks for the home and farm applicators using restricted pentachlorophenol products are described below in this section for the various exposure situations.

The Agency has determined that the registrations of home and farm use pentachlorophenol products may be continued only if these products are classified as restricted. The additional training and experience required of the applicator of a restricted use pesticide should help to assure that these products are applied only when indicated and with the appropriate safeguards. In addition, as discussed in Section VI.B of this document, the Agency will also require that all pentachlorophenol labels include a statement warning users of the potential fetotoxic effects.

The Agency considered cancelling registrations of pentachlorophenol for home and farm use. The acute toxic effects of chemical alternatives, which home and farm users might choose, were discussed in the PD 2/3 (pp. 367-379). However, long term potential toxic effects of exposure to the alternative chemicals have not yet been studied. It is possible that these chemicals might be just as toxic or more toxic for chronic effects than pentachlorophenol. The Agency will request data from the registrants on all the chemical alternatives for home and farm uses of pentachlorophenol. (See Section VIII of this document.) Also, the alternative chemicals cost more, some have not been shown to be as efficacious as pentachlorophenol, some may impart an objectionable color to the wood, and some do not allow for subsequent painting of the treated surfaces (PD 2/3 pp. 498-512).

When the studies on the chronic toxicity of alternative chemicals are received, the Agency will evaluate the data and will then determine if further regulatory action is necessary.

Because the Agency is concerned about potential hazards due to cresote exposure to applicators using creosote for railroad tie repair, the Agency is also requiring creosote products for this use to be for restricted use also under the category of home and farm use. Even where this frequent process of applying creosote by brushing or spraying is automated, the applicator may still be involved, for example, in mixing, cleaning equipment, or repairing equipment which fails or jams. In all situations involving application, the applicator should be trained in the safe use and handling of these toxic pesticides. The applicator may also work under the supervision of a certified applicator. The Agency has concluded that only with these restrictions and other restrictions presented in this PD 4 for home and farm use will the benefits of use of home and farm products containing creosote, including those for railroad tie repair, outweigh the risks.

3. Interior Application Prohibited

Exposure/Risk: The Agency expressed concern in the PD 2/3 about the potentially high inhalation exposure to individuals from home and farm use of creosote and pentachlorophenol applied indoors. Dermal exposure to creosote and pentachlorophenol was assumed to be the same for indoor as for outdoor application.

Due to insufficient data, the Agency did not evaluate the risks due to creosote exposure, but assumed the risk could be significant.

Regarding exposure to pentachlorophenol, the extent of dermal exposure during home and farm applications is dependent upon the care with which the product is applied. The Agency estimated that homeowners may spill amounts of pentachlorophenol formulation ranging from 1 drop (0.05 ml) to 6.0 ml on their skin during one brush-on application period (PD 2/3, p. 655). The Agency estimated that the total lifetime oncogenic risks to the home and farm applicators from dermal exposure to the pentachlorophenol formulation ranged from 1.0×10^{-6} to 1.3×10^{-4} for intermittent indoor application (PD 2/3 pp. 330 and 672). For dermal exposure and for exposure to pentachlorophenol vapors, the MOS for teratogenic/fetotoxic effects ranged from 6 to 400 (PD 2/3, pp. 660 and 672).

PD 2/3 Proposal: To eliminate this particular exposure from interior application of creosote and pentachlorophenol, the Agency proposed the following prohibition on interior home and farm use of these products:

> The application of creosote and pentachlorophenol
> products indoors is prohibited.

Final Regulatory Position and Rationale: Based on acute animal studies (Gaines, 1969) discussed in Section II of this document, the Agency reassessed the dermal absorption rate for pentachlorophenol in organic solvents (Zendzian, 1981) and determined that the dermal absorption rate was 50% rather than the previously assumed 10% (PD 2/3, p. 337). Based on inhalation exposure data submitted by USDA (1981) and discussed in Section II of this document, the ambient air concentration levels during the application of pentachlorophenol were estimated to be 34 to 140 ug/m^3 instead of the previously assumed 40 ug/m^3 (PD 2/3, p. 330). Also, the estimate of the protection afforded by gloves has decreased from 99% (PD 23/3) to 90% as described in Section II of this document.

These changes in pentachlorophenol dermal absorption rate and inhalation exposure significantly increase the oncogenic and fetotoxic risks from exposure to pentachlorophenol from indoor application by home and farm users as compared to that calculated in the PD 2/3.

Therefore, in order to protect the home and farm applicator, the Agency has concluded that labels for home and farm uses of creosote and of pentachlorophenol must, in addition to the statement regarding restricted use, include the following information allowing outdoor application but prohibiting indoor application.

> Avoid inhaling vapors. If inhalation of vapors cannot be avoided, appicators must wear a properly fitting well-maintained half-mask canister cartridge respirator which is MSHA/NIOSH-approved for organic vapors and acid gases (pentachlorophenol) or for polynuclear aromatics and organic vapors (creosote). Do not apply in interiors.

If a certified applicator wears gloves (as required below) and a respirator while applying pentachlorophenol formulations (assume 5%) outside but in small crawl spaces under homes, the potential oncogenic risk is 6.2×10^{-6} and the potential teratogenic/fetotoxic Margin of Safety is 12 (Rispin, April 18, 1984). It is assumed that the home and farm applicator applies pentachlorophenol for a 2-week period once every 3 years (Burnam, 1983). If, however, the applicator is employed doing odd jobs and uses pentachlorophenol more frequently (assume 120 days per year for a 30-year working lifetime), the estimated oncogenic risk is 2.1×10^{-4} (wearing gloves) and the Margin of Safety for fetotoxic effects is 12 (Saito, June 6, 1984).

The Agency is concerned about these potential oncogenic and fetotoxic riskes, but has concluded that requiring applicators to be trained in the handling of these pesticides and requiring a statement on the pesticide label that pregnant women should not use pentachlorophenol products will protect the public such that continued use of home and farm products will not result in the risks of use outweighing the benefits. The prohibitions and the protective measures presented throughout this Section (VI.E) are necessary to assure that exposure of individuals to all formulations of creosote and pentachlorophenol and their vapors will be reduced to levels such that the risks of use do not outweigh the benefits. When toxicity studies on chemical alternatives to pentachlorophenol are received, the Agency will evaluate the data and will take further regulatory action if it is deemed necessary.

4. Use of Protective Gloves

Exposure/Risk: Risks associated with exposure to all of the oncogenic or mutagenic components of creosote could not be quantified. Athough there are many reports of incidences of human skin cancer among creosote applicators (PD 2/3, p. 36), there are no studies available which can be used for a quantitative risk extrapolation of low levels of exposure.

The Agency estimated in the PD 2/3 (p. 672) that the total lifetime oncogenic risks to the home and farm applicators from dermal exposure to pentachlorophenol ranged from 1.0×10^{-6} to 1.3×10^{-4} for both indoor and outdoor application; the fetotoxic MOS ranged from 6 to 400 for indoor application and from 6 to 650 for outdoor application.

PD 2/3 Proposal: To reduce the risk caused by dermal exposure, the Agency proposed the following in the PD 2/3:

> All applicators using pentachlorophenol and creosote for home and farm uses must wear gloves impervious to these pesticides (e.g., rubber) in all situations when dermal contact with them is possible (e.g., handling treated wood).

Implementation of this modification for home and farm application would reduce the dermal exposure from hand contact by 99%. Using gloves, the oncogenic risk from dermal exposure for both indoor and outdoor applications of pentachlorophenol was in a range of 1.0×10^{-8} to 1.3×10^{-6}, the MOS for fetotoxicity for dermal and inhalation exposure to pentachlorophenol ranged from 360 to 900 for indoor application, and 560 to 7,100 for outdoor application (PD 2/3, pp. 660 and 672).

Final Regulatory Position: As explained previously (Section VI.E.3), the Agency will prohibit application of pentachlorophenol and creosote in residential interiors, but will allow outdoor application providing the labels indicate that certain precautions are to be taken. The Agency has recalculated the risks to home and farm users from outdoor exposure to pentachlorophenol and has found, if gloves are worn, that the oncogenic risk will be 6.2×10^{-6}, assuming the home and farm user applies pentachlorophenol for a period of two weeks once every three years (Burnam, 1983). The MOS for teratogenic/ fetotoxic effects is 12 (Rispin, April, 18, 1984). If the home and farm user does odd jobs and applies the pentachlorophenol 120 days per year for a 30-year working lifetime, the potential oncogenic risk is estimated to be 2.1×10^{-4} (with gloves); the MOS is 12 (Saito, June 6, 1984). The increased dermal absorption rate and increased inhalation exposure (Section II) were taken into account in this calculation. No data were available to calculate risks due to creosote exposure.

In order to reduce dermal absorption and protect the home and farm applicator, the Agency has concluded that labels of all formulations of creosote and pentachlorophenol must be amended to include the following information:

> Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (for example, during the actual application process and when handling freshly treated wood).
>
> Acceptable materials for gloves for pentachlorophenol and creosote products for home and farm use are polyvinyl

chloride, polyvinyl acetate, neoprene, NBR (Buna-N), nitrile (pentachlorophenol only).

This required label language states "where dermal contact is expected" instead of "where dermal contact is possible" (PD 2/3 proposal), recommends various types of glove materials instead of rubber (Silkowski, 1982), and describes the additional exposure situation as "during the actual application process." This requirement will, as would the PD 2/3 proposal, reduce dermal exposure from hand contact with pentachlorophenol and creosote by 90% (Rispin, April 24, 1984). The rationale for the changes in wording from the PD 2/3 proposal was discussed in Section VI.C.5 of this document. Acceptable materials for gloves for pentachlorophenol were recommended by the wood preserving industry (AWPI, June 17, 1982) and by the University of Washington (Silkowski, 1982). Rubber gloves are not now recommended for the home and farm formulations of creosote and pentachlorophenol based on this information. As discussed in Section VI.C.2 of this PD 4, the Agency will require that the registrants submit data on the effectiveness of protection of certain materials in contact with creosote formulations.

The Agency has concluded that benefits of home and farm use of pentachlorophenol and creosote outweigh the risks of use only if modifications to the terms and conditions of registration are made by the registrants as outlined in Section VIII of this document. When studies on the toxicity of chemical alternatives are submitted by the registrants, the Agency will evaluate the data and take further regulatory action if deemed necessary.

5. Protective Clothing

Exposure/Risks: Home and farm products containing creosote or pentachlorophenol are typically applied by brush, dip or spray methods. The Agency assumed (PD 2/3 p. 665) that the manual spray operation presents, by far, the greatest opportunity for exposure to the applicator. However, the risks associated with spraying these wood preservatives cannot be quantified, because of the lack of quantitative exposure data.

PD 2/3 Proposal: To reduce exposure and risk from the brush, dip, or spray methods of application of creosote or pentachlorophenol for home and farm use, the Agency proposed in the PD 2/3 that certain protective clothing be worn by the certified applicators:

> All certified applicators who apply creosote or pentachlorophenol by the spray method must wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots, and a properly maintained half-mask canister or cartridge respirator designed for pesticide use, and all certified applicators who apply creosote or pentachlorophenol by other application processes (e.g., brush-on) must wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing.

As assumed in the PD 2/3, the use of the protective clothing would reduce the total dermal exposure by 80%; the use of a respirator would reduce the inhalation exposure by 90%, resulting in a significantly reduced risk.

Final Regulatory Position and Rationale: Regarding protective clothing for certified applicators, the Agency has determined that labels of creosote and pentachlorophenol formulations must be amended to include the following information:

> Spray applicators must wear protective clothing (including overalls, jacket, gloves and boots) impervious to the wood treatment formulation, and a respirator, head covering and goggles when spraying. Applicators who apply creosote and pentachlorophenol by other application processes (e.g., brush-on) must wear disposable coveralls or other suitable impermeable protective clothing. Launder non-disposable protective clothing separately from other household clothing

Respirators acceptable for spray applicators of creosote and pentachlorophenol were described in Section VI.C.2 of this document. Examples of acceptable materials for protective clothing required during application and handling of restricted use formulations of creosote and pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene NBR (Buna-N), and nitrile (pentachlorophenol only). Nitrile is also assumed to be acceptable for disposable coveralls for creosote applications. This information about respirators and materials for protective clothing must also be stated on the label.

This requirement will reduce risks to certified applicators by providing instructions regarding protective clothing and a respirator to certified applicators who are allowed to apply the Restricted Use formulations of creosote and pentachlorophenol. The types of materials for the protective clothing are more clearly delineated in this final determination than in the PD 2/3 proposal, based on information provided by the wood preserving industry and evaluated by the Agency (AWPI, June 17, 1982). The additional protective clothing of "head covering and goggles when spraying" is expected to reduce exposure even further.

Without these label modifications the Agency has concluded that the benefits of use of the Restricted Use formulations of pentachlorophenol and creosote would not outweigh the risks.

The use of this protective clothing will reduce total dermal exposure by 80% and inhalation exposure by 90%, resulting in a reduced risk. Because the Agency has no exposure data for this spray application activity, registrants will be required to submit data on inhalation and dermal exposure from home and farm spray applications of pentachlorophenol at several pentachlorophenol concentrations. These data will enable the Agency to quantitate the risk associated with this activity and take further regulatory action if deemed necessary.

As discussed in Section VI.C.2, the Agency will reevaluate the appropriateness of recommending certain materials for protection from creosote formulations upon receipt of data required to be submitted by the registrants on the permeability of materials to creosote formulations.

6. Disposal of Clothing and Pesticide Formulations

Exposure/Risk: As previously mentioned in this document, although the Agency has not quantified the risks, there are potential risks resulting from pentachlorophenol and creosote adhering to clothing and shoes and being transported into the home following home and farm uses. This exposure could pose a risk to the applicators' families.

PD 2/3 Proposal: To reduce risks from this potential exposure, the Agency proposed in the PD 2/3 that applicators applying creosote or pentachlorophenol solutions (home and farm use) follow certain instructions regarding disposal of clothing.

Specifically, the Agency proposed the following:

> All applicators must dispose of worn-out protective clothing in accordance with the instructions for pesticide container disposal.

Final Regulatory Position and Rationale: The Agency has concluded that the labels of all formulations of creosote and pentachlorophenol for home and farm use must be amended to include the following information:

> Protective clothing must be changed when it shows signs of contamination. Dispose of worn-out protective clothing and workshoes or boots in any general landfill, in the trash or in any other manner approved for pesticide disposal.

This wording will reduce exposure to the worker by providing instructions for changing protective clothing. The rationale for the more specific directions for disposal of worn-out protective clothing was described in Section VI.C.6 of this document.

This requirement will accomplish the reduction of exposure to applycators' families from these wood preservatives such that the benefits of use will exceed the risks.

As described in Section VI.C.6 of this PD 4, the Agency published PR Notice 83-3 (March 29, 1983) informing registrants of proper instructions to include on pesticide labels regarding storage and disposal of pesticide formulations. The Agency therefore requires, as part of this conclusion to the wood preservatives RPAR, that registrants amend the labels of formulations containing pentachlorophenol and cresote which are for farm use or railroad tie repair use only to include the following information:

> Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your state Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

That notice as well as PR Notice 84-1 (Feb. 17, 1984) addressed disposal of formulations for household/domestic use. The Agency will require, as part of the regulatory action, that labels of formulations containing pentachlorophenol and creosote for household/domestic use be amended to include the following information:

> Securely wrap original pesticide container in
> several layers of newspaper and discard in
> the trash. Do not reuse empty container.

7. Warnings about Eating, etc., during Application

Exposure/Risk: Although the risks due to accidental ingestion of wood preservatives by smoking, drinking or eating during home and farm applications for pentachlorophenol and creosote have not been quantified, the Agency has, however, determined that there is a potential for adverse human health effects in these use situations.

PD 2/3 Proposal: To eliminate risks from this potential exposure, the Agency proposed the following in the PD 2/3:

> Eating, smoking and drinking are prohibited during the
> application of creosote or pentachlorophenol products.

Final Regulatory Position and Rationale: The Agency has concluded that labels for these home and farm pentachlorophenol products must be amended to include the following information:

> Applicators must not eat, drink or use tobacco
> products during those parts of the application process
> which may expose them to the treatment formulation.
> Wash thoroughly after skin contact, and before eating,
> drinking, use of tobacco products, or using restrooms.

This requirement will greatly reduce or eliminate the applicators' exposure during the application process.

The rationale for adopting this wording was discussed previously in Section VI.C.7 of this document.

8. Contamination of Food, Feed, and Water

Exposure/Risk: The Agency was concerned that food, feed, and water may become contaminated from home and farm use of pentachlorophenol or creosote products and that there could be direct contact with domestic animals or livestock.

PD 2/3 Proposal: The PD 2/3 proposed the following label amendment:

> Do not use creosote or pentachlorophenol in a manner
> which may result in direct exposure of domestic animals

> or livestock, or in the contamination of food, feed, or drinking or irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feed lot bins, and watering troughs).

Final Regulatory Position and Rationale: Upon review of the PD 2/3 proposed label language, the Agency has concluded that the examples of food crates, irrigation flumes, etc. should be deleted, not only because the label language is self-explanatory but also because the Agency does not want the application prohibitions to be limited to those particular wood products. There may be other wood items to which pentachlorophenol or creosote could be applied and thereby cause direct exposure to animals or result in the contamination of food, feed, or water.

Taking these considerations into account, the Agency has concluded that labels must be amended on all creosote and pentachlorophenol products for home and farm use to include the following information.

> Do not apply where there may be direct contact with domestic animals or livestock, and where there may be contact with food, feed, or drinking and irrigation water.

This requirement will eliminate the possibility of the liquid formulations coming into direct contact with food, feed, or water during application. Precautions regarding intended uses of wood or wood products which have been treated with pesticides are discussed below in Section VI.E.9.

The Agency has determined that this label amendment is necessary so that benefits associated with home and farm use of pentachlorophenol and creosote will not be outweighed by the risks.

9. Other Restrictions on Application and Intended Use of Treated Wood

Exposure/Risk: Human exposure to wood preservative chemicals from contact with the wood which has been treated is also of concern to EPA. Construction workers, home repairmen, and residents of homes containing treated wood may all be exposed to wood preservatives from a variety of treated products, often without being aware of exposure to the pesticides. Although the Agency is not able to quantify the risk to the general public from all exposure to treated wood products, such exposure is likely to be significant.

PD 2/3 Proposal: To protect persons who would be exposed from wood treated by a home and farm use product, the Agency proposed that the following be included on pentachlorophenol and creosote labels.

> The application of creosote and pentachlorophenol products to wood intended for interior use is prohibited, except for

those support structures (e.g., foundation timbers, pole supports and the bottom six inches of stall skirtboards) which are in contact with the soil in barns, stables, and similar sites and millwork (pentachlorophenol only) which has outdoor surfaces (e.g., doorframes, windows, and patio frames).

Limitations on the use of treated wood were considered as part of a TSCA rule. The Agency recommended that a rule be promulgated to require labeling of the treated wood product. The label information under consideration included additional warnings concerned regarding use of gloves when handling treated wood, protective measures to be taken when sawing treated wood, a prohibition on use of treated wood which may contact domestic animals, food, feed, or water, and a prohibition on burning treated wood (PD 2/3, p.720).

Final Regulatory Position and Rationale: Regarding use of treated wood in interiors, AWPI (#36H:30000/28C) commented that EPA lacks the authority under FIFRA to regulate the end uses of treated wood, that the restriction is an attempt to control end uses of treated wood through FIFRA labeling, and that Congress did not intend that the end product, whether an agricultural product or wood after being treated with the preservative, continue to be regulated under FIFRA.

The Agency has determined that FIFRA gives the Agency broad authority to regulate pesticides such that their use does not cause unreasonable adverse effects (FIFRA Sections 3(c)(5), 3(c)(6), and 12). Pursuant to that authority, the Agency may require that use restrictions be included on the labels of pesticide products addressing precautions to be taken regarding appropriate limitations on the use of products treated with pesticides.

AWPI (#36H:30000/28C) further commented that EPA has failed to show that a hazard to human or animal health has been demonstrated from interior uses of creosote or pentachlorophenol treated wood.

As discussed in Section VII.A.4 and VII.A.5 of this PD 4, acute effects to man and domestic animals from interior use of these chemicals have been adequately demonstrated; the potential for chronic effects also is discussed in these sections. As indicated by USDA (1981) two coats of an effective sealer reduces vaporization of pentachlorophenol by 85% (Day, December 9, 1983). This reduction is consistent with data submitted by Dr. Levin of the University of California (70:30000/28C) and Jackson and Stratton of the California Department of Health Services (87:30000/28C) on the reduction of vaporization of pentachlorophenol by the use of two coats of a sealer (Day, Aug. 16, 1983). Therefore the Agency will require that, for limited interior use of treated wood, two coats of an effective sealer should be applied.

Because the Agency is concerned about potential unreasonable adverse effects from exposure to wood products treated with pesticides, the Agency has determined that certain actions must be taken to limit exposure of the general public to wood preservatives released from wood after it is treated. To assure that adequate warnings and use restrictions for treated wood are presented on labels of home and farm use products containing pentachlorophenol or creosote, the registration of these products must be amended to require the following information on the label:

> Do not apply to wood intended for use in interiors except for those support structures which are in barns, stables, and similar sites and which are subject to decay and insect infestation; and millwork (pentachlorophenol only) which has outdoor surfaces (e.g., door frames, windows and patio frames). Interior surfaces of the treated wood should be sealed with two coats of an appropriate sealer.
>
> Do not apply pentachlorophenol or creosote to wood intended for farrowing or brooding facilities. Do not apply pentachlorophenol or creosote to wood intended to be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood. Pentachlorophenol or creosote may be used to treat wood intended to be used in interiors of farm buildings where domestic animals or livestock are unlikely to crib or lick the wood, if two coats of an appropriate sealer will be applied.
>
> Do not apply to wood intended to used in a manner in which the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.
>
> Do not use this product to treat wood intended to be used for cutting boards or counter tops.
>
> Do not use this product to treat wood intended for construction of those portions of beehives which may come into contact with the honey.
>
> Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with public drinking water, except for those uses involving incidental contact such as docks and bridges.
>
> Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.
>
> Wood to be treated with this product should be cut to size before treatment. If it is necessary to saw or machine wood after treatment, wear goggles to protect the eyes from flying particles and a dust mask to

> avoid inhaling sawdust from the treated wood. If oily preservative or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household laundry.
>
> Contact with treated surfaces should be avoided even after the preservative has dried. When handling treated wood, wear tightly woven coveralls and gloves which are impervious (e.g., vinyl coated) to the pesticide.
>
> Wash exposed skin thoroughly after contact with treated wood, and before eating, drinking or using tobacco products.
>
> Wood which has been treated with this product should be disposed of by burial or ordinary trash collection. Do not burn treated wood in an outdoor fire or in stoves or fireplaces, because toxic chemicals may be produced as part of the smoke and ashes.
>
> This product should not be used to treat wood which will be in frequent or prolonged contact with skin, unless the wood will be treated with an effective sealer.
>
> Urethane, epoxy, and shellac are acceptable sealers for all creosote-treated wood. Urethane, shellac, latex expoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

These use restrictions should provide substantial protection from exposure to creosote and pentachlorophenol through use of a home and farm use product. The Agency has determined that such additional protection is necessary to avoid unreasonable adverse effects to the population. Detailed discussion of the reduced exposure which can be expected from implementation of these restrictions can be found in Section VII.A. of this PD 4, which discusses the Consumer Awareness Program.

F. Brush-on Treatments of Inorganic Arsenicals

Brush-on application refers to the commercial application of the inorganic arsenicals to the cut-ends of treated wood, an activity which usually occurs only at construction sites. These inorganic arsenical formulations have not been generally available for purchase by the homeowner or farmer because of current marketing practices.

1. Unclassified Use

Exposure/Risk: The Agency was concerned about exposure to applicators from improper handling of the inorganic arsenicals during brush-on treatments. However, the Agency had no means of quantifying the risk attributable to careless handling procedures.

PD 2/3 Proposal: To assure the proper and safe handling of inorganic arsenical formulations for brush-on treatments, the Agency proposed the following labeling modification on the PD 2/3:

> **Restricted Use Pesticide:** For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

Final Regulatory Position and Rationale: Based on comments by USDA (1980) that restricted use classification for brush-on treatments of the inorganic arsenicals was not necessary, the Agency reevaluated the exposure situation for this activity. For the brush-on application of inorganic arsenical products, the Agency has concluded that these products will remain unclassified only if the labels are modified to indicate that mixing and diluting are prohibited and that they are only for commercial construction application to the cut ends of pressure-treated wood.

Specifically, the Agency has determined that in order for the benefits of use to exceed the risks, formulations of the inorganic arsenicals for brush-on treatments must have the labels amended to include the following statements:

> For application to the cut ends of pressure-treated wood only. Do not dilute or mix with other products. For commercial construction use only. Not for household use.

The Agency believes that with proper labeling, the ready-to-use products for the brush-on application of the inorganic arsenicals can be handled safely. The labels would also be modified to include the listing of protective measures that must be taken as described in the sections that follow (gloves, protective clothing, etc.). The calculated potential risks are also presented below in those sections.

2. Materials for Protective Gloves

Exposure/Risk: The exposure to the inorganic arsenicals by brush-on treatment applications is caused by spilling or otherwise coming into contact with the liquid formulations. The dermal exposure in this situation was estimated to be 3 ug/kg/day, and the lifetime dermal oncogenic risk to brush-on applicators is 1.2×10^{-2}; the teratogenic/fetotoxic MOS was estimated to be 1,667 (PD 2/3, p. 666). The Agency has assumed that inhalation exposure would be negligible because aqueous solutions (with low vapor pressure) are used and brush-on treatments are applied outdoors using very small volumes of treatment solution (PD 2/3, p. 666).

PD 2/3 Proposal: To reduce the risk caused by dermal exposure, the Agency proposed (PD 2/3) that:

> All applicators must wear gloves impervious (e.g., rubber) to the inorganic arsenical solutions in all situations where dermal contact with the pesticide is possible (e.g., handling treated wood).

During commercial brush-on treatments of the inorganic arsenicals to wood, there is a potential for dermal exposure to the pesticide. It was calculated in the PD 2/3 that wearing gloves will reduce the dermal exposure and thus oncogenic risk 99% from 1.2×10^{-2} to 1.2×10^{-4} and increase the teratogenic/fetotoxic MOS from 1,667 to 170,000 (PD 2/3, p. 672).

Final Regulatory Position and Rationale: The Agency has concluded that labels for brush-on formulations of the inorganic arsenicals must be amended to include the following information:

> Applicators must wear gloves (e.g., rubber, vinyl, or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood).

The recalculated risk based on the assumptions discussed in Section II for brush-on applications of inorganic arsenic is 2.8×10^{-4} (with gloves) (Rispin, April 18, 1984).

The required language is more specific about the types of materials appropriate for gloves and describes more specifically the exposure situations of concern.

This requirement for the use of gloves provides for the reduction in hand dermal exposure as did the PD 2/3 proposal. The rationale for the changes in the wording of the PD 2/3 proposal was discussed in Section VI.C.5 of this document. The types of materials appropriate for gloves were based on information submitted by the wood preserving industry (AWPI, June 17, 1982) and evaluated by the Agency. As previously mentioned (Section VI.C.2 of this PD 4), additional data will be required on the effectiveness of various materials used for gloves and protective clothing in preventing exposure to arsenic formulations.

3. Materials for Coveralls

Exposure/Risk: It is likely that, during the brush-on applications of inorganic arsenicals, some spillage or splattering may occur on the arms and legs as well as the hands. Although the Agency has not quantified the applicator total dermal exposure during the brush-on application, there is the likelihood that splattering of the pesticide may occur, hence the risk could be significant.

PD 2/3 Proposal: To reduce total dermal exposure the Agency proposed the following in the PD 2/3:

> Applicators must wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing during the application process.

This modification would reduce risks to a greater degree than the risk reduction resulting from gloves alone. Gloves alone reduce dermal exposure from hand contact by 99% and total dermal exposure by 30%. If both gloves and coveralls are worn, total dermal exposure is reduced by 80%.

Final Regulatory Position and Rationale: The Agency has concluded that labels for brush-on formulations of the inorganic arsenicals must be modified to include the following information:

> Applicators must wear disposable coveralls (e.g., vinyl or polyethylene) or other similar impermeable protective clothing during the application process where dermal contact is expected.

This requirement is different from the PD 2/3 proposal in that vinyl has been substituted for nitrile as an appropriate material for the protective clothing based on information from the wood preserving industry (AWPI, June 17, 1982). The phrase "where dermal contact is expected" has been added to further define the exposure situation. The recommended materials for protective clothing will be reevaluated when data are received from the registrants on the permeability of materials when in contact with arsenic formulations.

4. Warnings about Eating, etc., during Application

Exposure/Risk: Although the risks due to accidental ingestion of wood preservatives by smoking, drinking, or eating during commercial brush-on applications of the inorganic arsenicals have not been quantified, the Agency determined in the PD 2/3 that there is a potential for adverse human health effects in these use situations.

PD 2/3 Proposal: To eliminate risks from this potential exposure, the Agency proposed (PD 2/3) the following:

> Eating, drinking and smoking during the application of the inorganic arsenical products are prohibited.

Final Regulatory Position and Rationale: The Agency has concluded that brush-on formulations of the inorganic arsenicals must have the labels amended to include the following information:

> Applicators must not eat, drink, or use tobacco products during those parts of the application process which may directly expose them to the treatment solution. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

This restriction will greatly reduce or eliminate the applicators' accidental exposure during the application process.

The rationale for revising the PD 2/3 proposal was discussed in Section VI.C.7 of this document.

5. Disposal of Clothing and Pesticide Formulations

Exposure/Risk: Although the Agency has not quantified the risks, there are potential risks resulting from the inorganic arsenicals adhering to clothing and shoes, and not being disposed of properly.

PD 2/3 Proposal: To reduce risks from this potential exposure, the Agency proposed the following:

> All applicators applying brush-on inorganic arsenicals must dispose of worn-out protective clothing in accordance with the instructions for pesticide container disposal.

Final Regulatory Position and Rationale: The Agency has concluded that labels of the brush-on formulations of the inorganic arsenicals must be amended to include the following information:

> Protective clothing must be changed when it shows obvious signs of contamination. Launder non-disposable protective clothing separately from other household clothing. Dispose of worn-out protective clothing in a manner approved for pesticide disposal and in accordance with State and Federal regulations.

This requirement will reduce exposure to the workers and clarifies the Agency's intention about pesticide disposal as described earlier in Section VI.C.6 of this document. Also, additional instructions regarding changing and laundering any non-disposable protective clothing belonging to the applicator are provided.

In addition, as described in Section VI.C.6 of this PD 4, the Agency will also require that labels of the brush-on formulation of the inorganic arsenicals must be amended to include the following information as stated in the Agency's PR Notice 83-3 (March 29, 1983):

> Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

6. Intended Interior Use and Food/Feed/Water Issue

Exposure/Risk and PD 2/3 Proposal: The Agency was concerned about exposure to individuals from brush-on uses of the inorganic arsenicals on wood intended for interior use and proposed in the PD 2/3:

> Do not apply brush-on inorganic arsenical solutions to wood intended for indoor use, except for those support structures (e.g., foundation timbers, pole supports and the bottom six inches of stall skirtboards) which are in contact with the soil in barns, stables and similar sites, all weather wood foundations, sills and plates and structural framing.

There were no exposure data available for these use situations, but the Agency determined it prudent to propose this prohibition.

The Agency also proposed in the PD 2/3:

> Do not use inorganic arsenicals in a manner which may result in direct exposure to domestic animals or livestock or in the contamination of food, feed, or drinking or irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feed lot bins, and watering troughs).

Final Regulatory Position and Rationale: The brush-on treatments of the inorganic arsenicals will be permitted to be used by carpenters at construction sites only for application to the cut-ends of arsenic pressure-treated wood. The Agency has concluded, therefore, that labels for the brush-on treatments of the inorganic arsenicals must be amended to include the following information:

> For application to the cut ends of pressure-treated wood only. Do not dilute or mix with other products. For commercial construction use only.

These prohibitions will effectively eliminate interior uses or other uses in which the wood treated by brush-on applicators of the inorganic arsenicals would come into direct contact with domestic animals or livestock or result in the contamination of food, feed, or drinking or irrigation water.

With these label modifications the Agency has concluded that the benefits of use of the brush-on formulations of the organic arsenicals will outweigh the risks.

G. Use of Salts of Pentachlorophenol for Sapstain Control

This Section discusses the Agency's position for regulating uses of sodium pentachlorophenate which is applied by non-pressure methods (spray or dip/flow) for sapstain control. Infestation by sapstain fungi increases the capacity of the wood to absorb moisture, making the wood more vulnerable to decay. Moreover, the discoloration caused by the sapstain is objectionable to wood users and reduces the market value of the wood (PD 2/3, p. 512).

1. Use Directions for Spray Applications of Sodium Pentachlorophenate

Exposure/Risk: The Agency expressed concern in the PD 2/3 about the high potential for dermal and inhalation exposure during the spray operations using sodium pentachlorophenate for sapstain control in the non-pressure treatment plants. The inhalation exposure occurs via inhalation of aerosolized sodium pentachlorophenate solution (PD 2/3, p. 589).

For spray operations, the total estimated lifetime oncogenic risk while spraying sodium pentachlorophenate for sapstain control was 1.9×10^{-3}; the fetotoxic MOS was 50 (PD 2/3, p. 589). This estimate was based on the exposure assumption that an applicator worked 8 hours per day near the spray booth where the maximum air levels (69 ug/m^3) of sodium pentachlorophenate were measured (PD 2/3, p. 322).

PD 2/3 Proposal: To reduce the risks to spray applicators, the Agency proposed in the PD 2/3 the following:

> All applicators who apply sodium pentachlorophenate formulations by the spray method must wear gloves and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.

An applicator wearing a respirator and gloves during the spray operation will significantly reduce the hand dermal exposure by 99% and inhalation exposure by 90%. The oncogenic risk during the spray operation of sodium pentachlorophenate for sapstain control would be decreased from 1.9×10^{-3} to 4.8×10^{-5} (PD 2/3, p. 657); the fetotoxic MOS would be increased from 50 to 2,000 (PD 2/3, p. 662) if the protective clothing (gloves and respirator) were worn during this activity.

The Agency assumed in the PD 2/3 that the applicators were being exposed to a mist (aerosolized solution) of sodium pentachlorophenate resulting from the spray application. Based on this assumption, the Agency concluded that the applicator was also exposed to the contaminant HxCDD in the mist and determined the applicator's exposure (worst case) to HxCDD based on measured air levels of sodium pentachlorophenate near the spray booth (PD 2/3, p. 322).

Final Regulatory Position and Rationale: The Agency conducted field investigations which established that the pesticide is mechanically applied to the wood in an enclosed spray booth, so that a mist near the spray booth would not normally be generated unless there were leaks in the system. In addition, the applicators (e.g., about three to four workers) are usually about 30 to

40 feet from the enclosed spray booth and, thus, would not be exposed to any significant amount of generated mist of sodium pentachlorophenate. However, the applicators may be exposed to sodium pentachlorophenate vapors (invisible evaporated chemical) measured at 12 ug/m^3 (PD/3, p. 322).

HxCDD has a low vapor pressure of 6.6×10^{-7} mm Hg (SAB, 1978), therefore workers 30 to 40 feet from the enclosed spray booth would not be expected to be exposed to HxCDD. Based on the fact that (1) the spray booth is enclosed and (2) HxCDD has a low vapor pressure, the Agency now assumes that the applicators 30 to 40 feet away from the spray booth are only exposed to the sodium pentachlorophenate vapors. Based on these revised exposure assumptions, the Agency recalculated the potential risks to applicators.

The sodium pentachlorophenate air concentration typically found in the area where a worker spends the majority of the time (30 to 40 feet from the enclosed spray booth) during an 8-hour work shift is 12 ug/m^3 (PD 2/3, p. 322). Based on this concentration the total inhalation exposure (without respirators) is 1.8 ug/kg/day (Day, Exposure Assessment 1982 and Rispin, April 18, 1984) and the MOS for fetotoxicity/teratogenicity effects from inhalation exposure is approximately 1700 ($\text{MOS} = \frac{\text{NOEL}}{\text{Exposure}} = \frac{3000\ \text{ug/kg/day}}{1.8\ \text{ug/kg/day}}$). Therefore, it would not be necessary for workers not in the immediate vicinity of the apparatus to wear respirators for protection against sodium pentachlorophenate vapors, because without them the margin of safety is adequate. However, gloves would be necessary to reduce dermal exposure during the handling of freshly treated wood as discussed below in this Section (VI.G.4).

Applicators in the vicinity of the spray apparatus could be exposed to both HxCDD and sodium pentachlorophenate mist and vapors. To estimate exposure, the Agency assumed the dermal absorption rate was 1.0% (Day, Dec. 9, 1983 and Rispin, April 18, 1984). The multi-stage risk model was used for risk estimation instead of the one-hit model as explained in Section II of this document. It was assumed that applicators used a 0.5% solution for spraying sodium pentachlorophenate (Rispin, April 18, 1984). No estimate could be made for dermal exposure to parts of the body other than the hands. However, it was assumed protective clothing would reduce dermal exposure by 80%.

For sodium pentachlorophenate, the recalculated oncogenic risk with gloves, protective clothing and a respirator (recalculated) is 3.8×10^{-5} and the fetotoxic risk is 2,000 as compared with 4.8×10^{-5} and 2,000, respectively, calculated for PD 2/3.

Therefore, if the applicator is in the vicinity of the spray booth during operation and a visible mist is present, the Agency has concluded that the applicator must wear a respirator for protection against both sodium pentachlorophenate and HxCDD. Gloves and protective clothing would also be necessary to reduce dermal exposure.

The Agency has determined that labels of sodium pentachlorophenate for sapstain control must be amended to include the following information:

> For the spray method of application, the spray apparatus must (1) be operated so as to minimize overspray (i.e., no visible mist) and (2) be free of leaks in the system. Should there be a visible mist, spray applicators in the vicinity of the apparatus (the zone in which the mist is visible) must wear a respirator and protective clothing (including overalls, jackets, boots, head covering impervious to the wood treatment formulation and goggles). Respirators must be properly fitting, well-maintained half-mask canister or cartridge respirators, which are MSHA/NIOSH-approved for organic vapors.

Examples of materials for protective clothing must be provided on the label as described in Section VI.C.2 of this document.

The final requirement will achieve the same reduction in inhalation exposure (by 90%) as the PD 2/3 proposed requirement. The proposed labeling language accomplishes the Agency's desire to reduce applicators' exposures while spraying sodium pentachlorophenate and requires the use of respirators only when necessary for protection against the visible mist (aerosolized solution) containing both the sodium pentachlorophenate and its HxCDD contaminate.

2. Use Directions for Emptying and Mixing

Exposure/Risk: In the PD 2/3, the Agency was concerned about the high inhalation and dermal exposure situations during the manual opening and emptying of bags of prilled (granular) or powder formulations of sodium pentachlorophenate in the preparation of treatment solutions.

PD 2/3 Proposal: The Agency proposed in the PD 2/3 to require closed systems for the emptying and mixing of all prilled (granular) and powder formulations of sodium pentachlorophenate to reduce inhalation and dermal exposures during this activity.

Final Regulatory Position and Rationale: The Agency's regulatory position and rationale for arriving at the final position is the same as that discussed in detail for dry pentachlorophenol in Section VI.C.3 of this document. The exposure and risk estimates are considered to be the same for dry sodium pentachlorophenate products as for dry pentachlorophenol products; i.e., airborne concentration is 2.4 mg/m^3, dermal exposure is 40 to 400 mg/hr, rate of dermal absorption for dry pentachlorophenol or sodium pentachlorophenate formulations is 1% and for HxCDD is 50%.

There are no "prilled" or flaked formulations of sodium pentachlorophenate presently registered. The Agency has determined that, within 30 days after publication of the Notice concluding the wood preservatives RPAR or 30 days after receipt of the Notice by registrant, whichever occurs later, the labels for powder formulations of pentachlorophenate used for sapstain control must be amended to include the following information:

> Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls) must be worn when emptying and mixing powder formulations of pentachlorophenate. After September 1, 1987, a closed system must be used when emptying and mixing powder formulations of pentachlorophenate. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.
>
> Respirators must be properly fitting, well-maintained half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors.

Examples of acceptable materials for gloves and coveralls which must be included on the labels are listed below in Section VI.G.5 "Use of Protective Clothing."

As described in Section VI.C.3, the use of closed systems will reduced exposure to ambient levels at 0.028 mg/m^3 based on Arsenault (1976), and thus risks will significantly be reduced. Potential oncogenic risks will be negligible and the MOS for teratogenic/fetotoxic effects will be 730 (Rispin, April 18, 1984).

3. Food/Feed/Water Issue

Exposure/Risk: The Agency expressed concern in the PD 2/3 that use of sodium pentachlorophenate for treating wood could result in direct exposure to domestic animals or livestock and in the contamination of food, feed, and water.

PD 2/3 Proposal: The Agency proposed in the PD 2/3:

> Do not use sodium pentachlorophenate in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins and watering troughs).

Final Regulatory Position and Rationale: Since the PD 2/3, the Agency has re-evaluated this PD 2/3 proposal regarding sapstain control. Sodium pentachlorophenate is used for control of sapstain only for posts and poles during air seasoning before they can be kiln dried and pressure-treated, and for green lumber during storage and transportation (PD 2/3, p. 513). Therefore, it would not be likely that the sodium pentachlorophenate would directly contact domestic animals or livestock or would contaminate food, feed, or drinking and irrigation water. In addition, because sodium pentachlorophenate is applied in an aqueous solution of 0.3 to 0.9% (PD 2/3, p. 322), it is expected that when the salt formulation evaporates the residues on the surface on the wood would be insignificant.

For these reasons the Agency has determined that it will not be necessary for labels of sodium pentachlorophenate to be amended as proposed in the PD 2/3 for this exposure situation.

4. Materials for Protective Gloves

Exposure/Risk: The Agency expressed concern that sodium pentachlorophenate treatment plant applicators may be dermally exposed to the wood treatment solutions when mixing the wood preservative and when cleaning and maintaining treatment equipment, such as vats. Applicators may also be exposed to the treatment solutions when handling freshly treated lumber or when applying (spraying, dipping) the preservative solution.

Although adequate experimental data are not available on the permeability of gloves to sodium pentachlorophenate, the Agency estimated that an applicator wearing gloves resistant to penetration would have significantly reduced (by 99%) exposures via the hands. Gloves would also provide some reduction in total dermal exposure. The reduction in total dermal exposure when gloves are worn, based on the reduction of skin area available to absorb the pesticide, is estimated to be about 30%.

PD 2/3 Proposal: The PD 2/3 proposed the following:

> All applicators using sodium pentachlorophenate for sapstain control must wear gloves impervious to sodium pentachlorophenate (e.g., rubber) in all situations where dermal contact with sodium pentachlorophenate is possible (e.g., handling treated wood).

For the dip/flow treatment, the oncogenic risk from dermal and inhalation exposure was estimated to be reduced from 7.1×10^{-4} without gloves to 7.1×10^{-6} with gloves; the MOS was increased from 59 to 6,000 (PD 2/3, p. 617).

For the spray method the oncogenic risk from both dermal and inhalation exposure was estimated to be reduced from 1.9×10^{-3} without gloves and respirator to 4.8×10^{-5} with gloves and respirator (PD 2/3, p. 657); the fetotoxic MOS was increased from 50 to 2,000 (PD 2/3, p. 662).

Final Regulatory Position and Rationale: The Agency has concluded that sodium pentachlorophenate labels must be amended to include the following information:

> All applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., during the application process and when handling freshly treated wood).

This requirement achieves reduction in hand dermal exposure as did the PD 2/3 proposal. Examples of acceptable materials for gloves are found below in Section VI.G.5 of this document ("Use of Protective Clothing"). These examples are required on the label.

Because of revised dermal absorption rates for sodium pentachlorophenate aqueous solutions (1%) and the use of the multistage risk model (Section II of this document), the Agency recalculated the risk due to exposure to the dip/flow treatment and found the risk (using gloves) to be 4.3×10^{-4} and the fetotoxic MOS to be 600. It was assumed aplicators were using a maximum of 5% sodium pentachlorophenate solution (Rispin, April 18, 1984).

The risk reduction to spray applicators of sodium pentachlorophenate when wearing gloves and a respirator was discussed previously in Section VI.G.1 of this document. Wearing both gloves and a respirator, the oncogenic risk is 3.8×10^{-5}; the fetotoxic MOS is 2,000 for workers in the immediate vicinity of the spray booth.

The required labeling language is expected to reduce the applicator's dermal and inhalation exposure to sodium pentachlorophenate. The rationale for the specific wording of the label statement is discussed in Section VI.C.5 of this document.

5. Use of Protective Clothing

Exposure/Risk: The Agency was concerned that individuals who enter or clean vats and other related equipment would be exposed (dermal and inhalation) to the sodium pentachlorophenate solutions or vapors. Due to insufficient data, risks were not quantified for applicators entering vats, but some finite risk was assumed.

PD 2/3 Proposal: The Agency proposed the following in the PD 2/3:

> All individuals who enter or clean vats and other related equipment must wear a neoprene-coated cotton or rubberized overall, jacket, gloves, and boots and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.

Final Regulatory Position and Rationale: The Agency has concluded that labels of sodium pentachlorophenate for sapstain control must be amended to include the following information:

> Individuals who enter, clean, or repair vats, tanks or other related equipment that is contaminated with the treatment solution must wear a respirator. In addition, where dermal contact is expected, these individuals must wear overalls, jackets, boots, and head covering impervious to the wood treatment formulation and goggles. Respirators acceptable for use by applicators of sodium pentachlorophenate must be properly fitting, well-maintained, half-mask canister or cartridge respirators, which are MSHA/NIOSH-approved for organic vapors. Examples of acceptable materials for protective clothing (e.g., overalls, jackets, head covering, boots, disposable coveralls and gloves)

> required during application and handling of sodium pentachlorophenate are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile.

The Agency believes that an individual wearing this protective clothing and a respirator while performing these activities will have a significantly reduced inhalation (respirator will reduce inhalation exposure by 90%) and dermal exposure (protective clothing will reduce total dermal exposure by 80%), resulting in significantly reduced risks.

This requirement provides the same reduction in exposures as the PD 2/3 proposal. The required label language also clarifies that the exposure situation of concern is "contact with equipment that is contaminated with the treatment solutions." The rationale for requiring the specific type of respirator and materials for protective clothing was discussed in Section VI.C.2 of this document.

6. Disposal of Clothing and Pesticide Formulations

Exposure/Risk: Although not quantified, as previously stated for other types of application of wood preservatives, there are potential risks from sodium pentachlorophenate pesticide-laden dust or treatment solutions which adhere to protective clothing and workshoes, and are transported from the treatment plant into the home. Bringing contaminated protective clothing and workshoes into the home at the end of the work day creates a potential exposure to the workers' families.

PD 2/3 Proposal: To eliminate or greatly reduce a potential source of wood preservative exposure in treatment plant workers' homes, the Agency proposed the following in the PD 2/3:

> All applicators must leave all protective clothing, workshoes or boots, and equipment at the plant at the end of the day. Worn-out protective clothing must be disposed of following the instructions for pesticide container disposal.

Final Regulatory Position and Rationale: The Agency has concluded that all labels of sodium pentachlorophenate for sapstain control must be amended to include the following information:

> Protective clothing must be changed when it shows signs of contamination. Applicators must leave all protective clothing, workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a general landfill, in the trash or in any other manner approved for pesticide disposal.

This requirement will eliminate this potential source of exposure in workers' homes.

The rationale for the change in the PD 2/3 proposal was discussed in Section VI.C.6 of this document.

In addition, as described in Section VI.C.6 of this document, the Agency requires that registrants amend the labels of sodium pentachlorophenate labels to include the following information as stated in the Agency's PR Notice 83-3 (March 29, 1983):

> Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

7. Warnings About Eating, etc., During Application

Exposure/Risk: As previously stated in this document, although the risks due to accidental ingestion of wood preservatives by smoking, drinking, or eating have not been quantified, the Agency has determined that there is a potential for adverse human health effects in these use situations.

PD 2/3 Proposal: To eliminate risks from this potential exposure, the Agency proposed the following in the PD 2/3:

> Eating, drinking and smoking are prohibited during the application of sodium pentachlorophenate for sapstain control.

Final Regulatory Position and Rationale: The Agency has determined that labels of sodium pentachlorophenate for sapstain contol must be amended to include the following information:

> Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or before using restrooms.

This requirement will greatly reduce or eliminate this type of accidental exposure during the application process. The rationale for the specific language in the requirement was discussed in Section VI.C.7 of this document.

8. Restricted Use

The Agency has adopted the PD 2/3 proposal regarding restricted use and has concluded that labels of sodium pentachlorophenate products for sapstain control must be amended to include the following information:

> RESTRICTED USE PESTICIDE: For sale to and use only by certified applicators or persons under their direct

supervision and only for those uses covered by the certified applicator's certification.

This requirement is the same as that proposed in the PD 2/3. The rationale for the PD 2/3 proposal and final position is the same as that discussed for pentachlorophenol, creosote and inorganic arsenicals in Section VI.C.9 of this document.

H. Non-Pressure Treatment Plant Dip/flow and Spray Uses of Pentachlorophenol

This Section presents the Agency's position for regulating non-pressure uses of pentachlorophenol for protection of millwork and plywood, particleboard and logs for log homes. Pentachlorophenol is applied to millwork and plywood primarily by dipping or spraying the wood (PD 2/3, p. 524). Dip treatment is also used to apply pentachlorophenol to logs which may be used in the construction of log homes. During the manufacture of particleboard, the pentachlorophenol solution, urea formaldehyde resin, and wax emulsion are mixed with the wood particles at the same time in a closed system (PD 2/3, p. 529).

1. Use Directions for Millwork and Plywood Spray Operations

Exposure/Risk: The Agency was concerned about a potential for high inhalation exposure during the spray operations in the non-pressure pentachlorophenol treatment plants for millwork and plywood. For non-pressure spray operations for millwork and plywood the total estimated lifetime oncogenic risk without protective measures from exposure to pentachlorophenol is 9.8×10^{-3} and the fetotoxic MOS is 10 (PD 2/3, p. 589).

PD 2/3 Proposal: To reduce the risks to millwork and plywood applicators, the Agency proposed the following in the PD 2/3 for non-pressure spray operations using pentachlorophenol for millwork and plywood:

> All applicators who apply pentachlorophenol to millwork and plywood by the spray method must wear gloves and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.

Wearing a respirator during the spraying operation would significantly reduce the applicator's inhalation exposure by 90%. During the spray operation of pentachlorophenol on millwork and plywood, the oncogenic risk would be decreased from 9.8×10^{-3} to 2.4×10^{-4} (PD 2/3, p. 657); the fetotoxic MOS would increase from 10 to 400, if both gloves and a respirator were worn (PD 2/3, p. 661).

Final Regulatory Position and Rationale: The Agency has determined that labels of pentachlorophenol products used for spray application on millwork and plywood must be amended to include the following information:

> For the spray method of application: spray apparatus must (1) be operated so as to minimize overspray (i.e., no visible

mist) and (2) be free of leaks in the system. Should there be a visible mist, spray applicators in the vicinity of the apparatus (the zone in which the mist is visible) must wear a respirator and protective clothing (including overalls, jackets, boots, head covering impervious to the wood treatment formulation and goggles). Respirators must be properly fitting, well-maintained half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors and acid gases.

Suggested materials for protective clothing must be included on the label as discussed in Section VI.C.5 of this document.

Gloves are also required as described below in Section VI.H.5 of this document.

The rationale for adopting this requirement for millwork and plywood and not the requirement that all applicators must wear respirators as proposed in the PD 2/3 is the same as that discussed in Section VI.G.1 of this document for sodium pentachlorophenate spray operations. In summary, (1) the process is automated and enclosed, and applicators are not continually exposed to a mist (aerosolized solution) as was assumed in the PD 2/3, and (2) applicators are not exposed to HxCDD vapors (invisible evaporated chemical) in the work area due to the low vapor pressure of 6.6×10^{-7} mm Hg (U.S. EPA, SAB, 1978). Workers may, however, be exposed to pentachlorophenol vapors, since pentachlorophenol has a vapor pressure of 1.6×10^{-4} mm Hg (U.S. EPA, SAB, 1978).

The majority of the workers spend most of their time 30-40 feet away from the apparatus and thus are not exposed to pentachlorophenol mist, but may be exposed to pentachlorophenol vapors. The inhalation exposure at 28 ug/m^3 pentachlorophenol air concentration for these workers is 4.1 ug/kg/day (Rispin, April 18, 1984) and the MOS for fetotoxic/teratogenic effects is 726 ($\text{MOS} = \frac{\text{NOEL}}{\text{Exposure}} = \frac{3000\ \text{ug/kg/day}}{4.1\ \text{ug/kg/day}}$). Therefore, a respirator would not be necessary for these workers for protection against pentachlorophenol vapors, since the Margin of Safety for this exposure is adequate. Gloves, however, would be necessary to reduce dermal exposure when handling the freshly treated wood.

Applicators in the immediate vicinity of the apparatus may be exposed to both pentachlorophenol mist (containing HxCDD) and pentachlorophenol vapors. The Agency assumes that the applicator is using a 2.5% pentachlorophenol solution (Rispin, April 18, 1984). The risks for this exposure were recalculated based on the new exposure assumptions discussed in Section II of this document. If there is a visible mist and workers are in the immediate vicinity of the apparatus, the revised oncogenic risk (using gloves, protective clothing, and a respirator) is 2.5×10^{-4} and the MOS is 23 (Rispin, April 18, 1984). Therefore, for these workers, protective gloves, clothing, and respirators are necessary.

The final requirement will achieve the same reduction in inhalation exposure (by 90%) as the PD 2/3 requirement, but will not impose the requirement for respirators in use situations where not warranted. If a visible mist is present there is exposure to pentachlorophenol and its HxCDD contaminant; therefore respirators would be necessary.

The Agency is concerned about the high potential oncogenic risks and low margin of safety for potential fetotoxic effects to millwork and plywood applicators exposed to pentachlorophenol. The Agency considered cancelling registrations of pentachlorophenol for millwork and plywood use and thus reevaluated the benefits of use of these products. Pentachlorophenol is applied to millwork and plywood to prolong the life of the wood by protecting the wood from decay. Pentachlorophenol is colorless, compatible with paints, stains, sealers and primers, and does not interfere with the adhesion of glazing compounds, caulkings or other sealants. The chemical alternatives which millwork and plywood applicators might choose to purchase are not as efficaceous as pentachlorophenol for all millwork and plywood use situations and may be more expensive (PD 2/3, pp. 523-528).

The Agency also reevaluated the risk estimates for oncogenicity and believes that a risk of 2.5×10^{-4} represents an extreme upper bound of the actual risk because applicators may not contact the treatment solutions dermally every day of their working life, nor would they receive inhalation exposure from a visible mist everyday of their working life. Thus, the estimated risk of 2.5×10^{-4} may be overstated, but, in the absence of information to the contrary, the Agency continues to assume that this estimate represents an upper limit of potential oncogenic risk.

Regarding the chemical alternatives to pentachlorophenol, the long-term potential toxic effects of exposure to the chemicals have not yet been studied. The Agency will therefore request data (chronic feeding, oncogenicity, reproductive effects, and teratology studies) as outlined in Section VIII of this document. When these studies are received, the Agency will evaluate the data and determine if further regulatory action is necessary.

Regarding potential fetotoxic risks, while the Agency believes that few women currently work as applicators in millwork and plywood treatment plants, the Agency cannot assume that no pregnant women are working or will work as applicators in these plants.

For the present the Agency believes that in addition to other required protective measures, (e.g., gloves, protective clothing, respirators), requiring millwork and plywood applicators to be trained and certified for the application of wood preservatives, and requiring a statement on the pesticide label that pregnant women should not use pentachlorophenol products will protect the applicator such that continued use for millwork and plywood applications will not result in fetotoxic risks outweighing the benefits of use.

2. Use Directions for Mixing and Emptying

Exposure/Risk: In the PD 2/3, the Agency was concerned about the high inhalation and dermal exposure situations during the manual opening and emptying of bags of prilled (granular) formulations of pentachlorophenol and in mixing the treatment solutions for millwork, plywood, and particleboard use. The risks due to exposure to pentachlorophenol during this activity were discussed in Section VI.C.3 of this document.

No exposure data were available for the mixing operations for the non-pressure application of pentachlorophenol in manufacturing particleboard. However, the Agency assumed there would be negligible inhalation exposure, because the application of pentachlorophenol to the wood particle mixture takes place in an enclosed resin blender. Specifically, the pre-mixed pentachlorophenol solution is pumped from its container directly into the resin blender. Here the pentachlorophenol is mixed with the wood particles along with the resin and wax (Esworthy, 1980).

PD 2/3 Proposal: The Agency proposed the following in the PD 2/3 regarding the emptying and mixing of prilled (granular) pentachlorophenol formulations:

> A closed emptying and a closed mixing systems must be used for all prilled (granular) formulations of pentachlorophenol.

The Agency determined that this proposal would reduce inhalation and dermal exposures during this activity for millwork and plywood, and particleboard use. The Agency assumed that risks would be greatly reduced if closed systems were used (PD 2/3, p. 561).

Final Regulatory Position and Rationale: For the reasons discussed in Section VI.C.3, for pressure-treatment uses the Agency has concluded that labels for prilled or flaked formulations of pentachlorophenol must be amended, within 30 days after publication of the Notice concluding the wood preservatives RPAR or 30 days after receipt of the Notice by the registrants, whichever occurs later, to include the following information:

> Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long sleeved cotton or disposable coveralls) must be worn when emptying and mixing prilled or flaked formulations of pentachlorophenol. After September 1, 1987, a closed system must be used when emptying and mixing prilled or flaked formulations of pentachlorophenol. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

Acceptable respirators and materials for protective clothing were discussed in Section VI.C.2 of this document. This information must also be included on the labels.

The discussion of new exposure data received since the publication of the PD 2/3, the reduction in exposure and risk if a closed system is used or if protective clothing is worn, and the Agency's rationale for adopting this final position were described previously in Section VI.C.3 of this document.

3. Indoor Use of Pentachlorophenol-Treated Millwork and Plywood, Particleboard, and Logs for Log Homes.

The Agency was concerned that there was exposure to humans and domestic animals from interior uses of pentachlorophenol-treated millwork and plywood, and particleboard, but that in a few situations the risks were estimated to be sufficiently low, in light of the benefits, to warrant continuation of some interior uses.

PD 2/3 Proposal: For millwork and plywood the Agency proposed in the PD 2/3:

> The application of pentachlorophenol products to wood intended for interior use is prohibited, except for wood which has outdoor surfaces (e.g., door frames, windows and patio frames).

For particleboard, the Agency proposed in the PD 2/3:

> The application of pentachlorophenol to particleboard intended for any interior use (e.g., kitchen cabinets) is prohibited.

Final Regulatory Position and Rationale: The Agency reevaluated this proposal and recognized that the exposure is likely to be low. There is no alternative for pentachlorophenol-treated particleboard, and the amount of pentachlorophenol-treated millwork, particleboard and plywood that is likely to be in the interiors of residences is minimal.

Millwork use includes window frames, door frames, sash screens, and molding in homes; pentachlorophenol water-repellent solutions (5%) are applied to exterior millwork products to prevent decay and/or insect infestation (PD 2/3, p. 523). Millwork is normally coated with paint or varnish (USDA, 1980), and, though exposure to the pentachlorophenol is unknown, it is expected to be low (USDA, 1980, p. 102). Sealers are known to reduce exposure by approximately 80% (Day, 1983).

Plywood is normally treated with a 5% pentachlorophenol solution (PD 2/3, p. 524). The plywood is often stained or coated with shellac. Also, the homeowner is not likely to invest the additional expense to buy pesticide-treated plywood for interior use; pentachlorophenol-treated plywood is used mainly as textured plywood siding to act as a water-repellant and mildewcide (PD 2/3, p. 524).

Treated particleboard represents about 0.005% of the particleboard produced in the U.S. (PD 2/3, p. 529). Only 0.65% pentachlorophenol (0.65% pentachlorophenol solids based on the oven dry weight of the wood) is used in the mixture of wood chips and resin (PD 2/3, p. 529). Therefore, though exposure to pentachlorophenol vapors in interiors is unknown, it is expected to be low. In addition, treated particleboard does not have widespread indoor use;

it is mainly used for kitchen cabinets and outdoor furniture in Hawaii where there is a high occurrence of above-ground termite attack.

As discussed in Section II of this document, instead of using the PD 2/3 estimate of 24 hours as the time spent in the home, the Agency revised the time to 15 hours (8 hours resting, 1 hour heavy work, and 6 hours of light work). This decrease in the time spent inside the home means decreased exposure and risk.

Based on these considerations, the Agency will not prohibit interior use of millwork, plywood, and particleboard treated with pentachlorophenol. The benefits of use exceed the risks due to exposure in this situation.

However, the Agency continues to be concerned that the application of pentachlorophenol on wood destined for interior use in enclosed residences, other than the exceptions noted above, may result in unacceptable inhalation and dermal exposure to residents of these dwellings. For example, approximately half of a log which has been dipped in pentachlorophenol for use in the construction of log homes intrudes into living areas. As noted in the PD 2/3 (p. 333), the Pesticide Incident Monitoring System (PIMS, 1978) received numerous reports of human health effects following the application of pentachlorophenol inside homes. Since the publication of the PD 2/3, the Agency has received additional reports of acute toxicity from interior use of pentachlorophenol-treated wood (Levin, Comment #60:30000/28C; Friends of the Earth, Comment #70:30000/28C; and Center for Disease Control, Comment #69:30000/28C). As discussed in Section III.A (Pentachlorophenol Issue #3) Jackson and Stratton of the California Department of Health Services (#87:30000/28C) reported increased pentachlorophenol concentrations in the urine of occupants of an office building constructed with pentachlorophenol pressuretreated beams. Pentachlorophenol was also found in the air inside the building at 10 ug/m^3 even after the beams had been sealed.

While the application of a sealant was considered in the PD 2/3 (p. 335) as a potential measure by which the vaporization of pentachlorophenol from treated wood might be adequately reduced, Amburgey and Williams, (Dec. 1982) who advise against the use of pentachlorophenol for log homes, reported that film forming finishes or sealers, if applied before one year after construction, may trap water in logs and lead to rapid and widespread decay, especially if these materials are applied to both the interior and exterior surfaces. Also, although USDA (1981) reports that sealers reduce vaporization by approximately 85%, there are no data on the length of time that the sealers are effective. Sealers may have to be reapplied at some later date.

Several alternatives to pentachlorophenol are cited in the literature: dip treatment with copper-8-quinolinolate or zinc naphthenate are recommended to protect log kits during transport and construction (Amburgey and Williams, Dec. 1982). Seasoned logs could also be pressure-treated with chromated copper arsenate (CCA) (Amburgey and Williams, Dec. 1982).

The Agency has not quantified the benefits derived from pentachlorophenol dip-treated logs. However, the Agency has determined that the acute risks to inhabitants of log homes in which the interiors are treated with pentachlorophenol are of such significance, particularly in light of available alternatives, that risks exceed the benefits. Therefore, the Agency requires that the following statement be included on the labels intended for the dip/spray commercial application of pentachlorophenol:

> Do not apply to logs which are intended for use in the construction of log homes.

4. Food/Feed/Water Issue

Exposure/Risk: The Agency was concerned that use of pentachlorophenol-treated millwork and plywood, and particleboard could result in direct exposure to domestic animals or livestock or contaminate food, feed, or water.

PD 2/3 Proposal: PD 2/3 proposed for millwork and plywood, and particleboard use:

> Do not use pentachlorophenol in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins and watering troughs).

Final Regulatory Position and Rationale: The Agency has reexamined these potential exposure situations for millwork and plywood, and particleboard which have been treated with pentachlorophenol.

Millwork, which may have outdoor surfaces, is usually treated with a 5% pentachlorophenol solution (PD 2/3, p. 524), presumably resulting in a minimal surface residue. According to USDA's "Biologic and Economic Assessment" (1980), it is normally coated with paint or shellac. This coating acts as a sealer, reducing exposure of humans or domestic animals to pentachlorophenol. It would be unlikely for treated millwork to be used in a way that pentachlorophenol would come into contact with livestock or where it could contaminate food, feed, or water.

Plywood is also treated with a 5% solution of pentachlorophenol (PD 2/3, p. 524) and is sometimes stained or coated with shellac if used in interiors, thus reducing dermal or inhalation exposure. As stated above regarding possible indoor exposure (Section VI.H.3) treated plywood is used mainly for outdoor siding (PD 2/3, p. 524). While it would be unlikely that consumers would use treated, unsealed plywood where it could come into contact with animals, any exposure of the pentachlorophenol surface residues to house pets, other domestic animals, or livestock would be assumed to be low. It is also not likely that treated plywood would be used in contact with food or animal feed. FDA has issued a regulation, however, stating that pentachlorophenol-treated wood may not contain greater than 50 ppm pentachlorophenol for uses in contact with raw agricultural products (21 CFR 178.3800). It is not likely that consumers would use it where it would be in direct contact with drinking and irrigation water, because the wood would decay, not having a sufficient concentration of preservative.

As previously stated (Section VI.H.3), treated particleboard is mainly used for kitchen cabinets and outdoor furniture in Hawaii where there is a high incidence of above-ground termite attacks. The resin used in the manufacture of particleboard acts as a sealant for the pentachlorophenol, and thus dermal or inhalation exposure to domestic animals would be expected to be low. It would not be likely to be used in situations where it would come into contact with livestock. Consumers also would not tend to use treated particleboard for construction of items which might come into contact with drinking or irrigation water, because it would decay, not having enough preservative. As stated above, FDA has issued a regulation regarding contact of pentachlorophenol-treated wood with raw agricultural products but not regarding contact of wood preservatives with food or animal feed. However, any contamination of food or animal feed from contact with treated particleboard is expected to be low; consumers are not expected to use treated particleboard for this use.

Based on the above considerations, the Agency will not require that labels be amended as proposed in the PD 2/3 for these exposure situations for millwork, plywood, and particleboard, as the Agency expects exposure and risk to be low.

5. Use of Gloves

Exposure/Risk: The Agency was concerned that treatment plant applicators of pentachlorophenol for millwork and plywood, and particleboard may be dermally exposed to the wood treatment solutions when mixing the wood preservatives and when cleaning and maintaining treatment equipment, such as vats, tanks, or other related equipment. Applicators may also be exposed to the treatment solutions when handling freshly treated wood.

The Agency was unable to quantify the hand dermal exposure resulting from most activities in which contact with these wood preservatives are likely to occur but did have exposure data on the dip/flow treatments of millwork and plywood. Although adequate experimental data are not available on the permeability of gloves to these wood preservatives, the Agency estimated that an applicator wearing gloves resistant to penetration by these wood preservatives would have significantly reduced exposures (by 99%) to these pesticides via the hands (Van Kozak, 1980). The reduction in total dermal exposure, based on the reduction of skin area available to absorb the pesticide, is about 30%.

For the dip/flow treatment of millwork and plywood, the risk (without gloves) is 7.1×10^{-3} and the fetotoxic MOS is 5.9 (PD 2/3, pp. 617 and 660).

PD 2/3 Proposal: To reduce dermal exposure, the Agency proposed for the use of pentachlorophenol for millwork and plywood, and particleboard:

> All applicators applying pentachlorophenol must wear gloves impervious to the wood treatment solution (e.g., rubber) in all situations where dermal contact with the treatment solutions is possible (e.g., handling treated wood).

Wearing gloves would reduce the risk to 7.1 x 10^{-5} and increase the fetotoxic MOS to 210 (PD 2/3, pp. 617 and 660). There were no dermal exposure data for particleboard treatment using pentachlorophenol, but the Agency assumed there would be a risk to workers handling the freshly treated particleboard.

Final Regulatory Position and Rationale: The Agency has determined that labels of pentachlorophenol formulations used for millwork and plywood, and particleboard must be amended to include the following information:

> Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (for example during the application process and when handling freshly treated wood).

As in the PD 2/3 (p. 576), the Agency will consider all workers associated with the treatment process to be applicators, regardless of their individual activities during the workday; all of the workers perform some aspect of pesticide application during the workday.

Materials acceptable for gloves are discussed in Section VI.C.2 of this document and will be required to be included in the label.

Wearing gloves will reduce dermal exposure from hand contact by 90% and thus accomplishes the Agency's desire to reduce the applicator's risk from exposure to these wood preservatives. The rationale for changing the wording of the PD 2/3 proposal to that of the final requirement was discussed in Section VI.C.5 of this document.

There were no dermal exposure data for application of pentachlorophenol to particleboard, but the Agency assumed there would be a risk to workers if they handled the fresh particleboard and that, therefore, gloves should be worn.

If gloves are worn for the dip/flow pentachlorophenol (5%) treatment of millwork and plywood, the risk (recalculated) is 4.3 x 10^{-4} and the fetotoxic MOS is 12. These risks are higher than those previously calculated in the PD 2/3 because of the new data, discussed in Section II. of this document, showing increased dermal absorption of pentachlorophenol from 10% to 50% (Zendzian, 1981) and a decrease in the protection afforded by gloves from 99% to 90% (Rispin, April 24, 1984). As was discussed above in Section VI. H.1. for millwork and plywood spray operations, the Agency is concerned about the potential oncogenic and fetotoxic risks associated with exposure to pentachlorophenol for these uses. However, the Agency has concluded that other required protective measures such as protective clothing as discussed in the next Section (VI.H.6) will further reduce total dermal exposure. The Agency also has concluded that the Restricted Use classification and label warning concerning potential fetotoxic effects will increase the margins of safety by promoting careful use of the product, or avoidance of use, such that there will be no unreasonable adverse effects. As discussed in Section VI.H.1, the Agency will reevaluate the use of pentachlorophenol for millwork and plywood when data on the potential toxicity asociated with the chemical alternatives are submitted by the registrants. At that time, the Agency will take further regulatory action if necessary.

6. Protective Clothing

Exposure/Risk: As discussed in the previous section on gloves (Section VI.G.5), the Agency was concerned about exposure to pentachlorophenol from applications to millwork and plywood, and particleboard during cleaning and maintaining equipment and handling freshly treated wood. Due to insufficient data, pentachlorophenol risks were not quantified for these activities.

PD 2/3 Proposal: To reduce potential risks, however, the Agency proposed the following in the PD 2/3:

> All applicators who enter or clean vats and other related equipment must wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots, and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.

The Agency believes that an applicator wearing this protective clothing and a respirator while performing these activities will have a significantly reduced inhalation exposure (by 90%) and total dermal exposure (by 80%), resulting in significantly reduced risks.

Final Regulatory Positions and Rationale: The Agency has determined that labels of pentachlorophenol formulations for millwork, plywood, and particleboard must be amended to include the following information:

> Individuals who enter, clean, or repair vats, tanks, or other related equipment that are contaminated with the treatment solution must wear a respirator. In addition, when dermal contact is expected, these individuals must wear overalls, jackets, boots, head covering impervious to the wood treatment formulation, and goggles.

Acceptable respirators and materials for protective clothing to be included on the label are listed in Section VI.C.2 of this document. As stated in the previous section (VI.H.5), gloves must also be worn.

This requirement for protective clothing, including head covering, provides the same or greater reduction in exposures as the PD 2/3 proposal. It further defines the possible exposures ("repair vats, tanks, or other related equipment."). The label amendment also defines acceptable types of respirators and gives examples of materials for protective clothing.

7. Disposal of Protective Clothing and Pesticide Formulations

Exposure/Risk: As previously stated, the Agency was concerned that, although not quantified, there are potential risks from pentachlorophenol containing pesticide-laden dust or treatment solutions which adhere to protective clothing and workshoes, and are transported from the treatment plant into the home. Bringing contaminated protective clothing and workshoes into the home at the end of the work day creates a potential exposure to the workers' families.

PD 2/3 Proposal: To eliminate or greatly reduce a potential source of wood preservative exposure in treatment plant workers' homes, the Agency proposed the following requirement in the PD 2/3 regarding protective clothing used during the application of pentachlorophenol to millwork, plywood, and particleboard:

> All applicators must leave all protective clothing, workshoes or boots, and equipment at the plant at the end of the day. Worn-out protective clothing must be disposed of in accordance with instructions for pesticide container disposal.

Final Regulatory Position and Rationale: The Agency has determined that labels of pentachlorophenol formulations for use on millwork, plywood, and particleboard must be amended to include the following information:

> Protective clothing must be changed when it shows obvious signs of contamination. Applicators must leave all protective clothing, workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a general landfill, in the trash or in any other manner approved for pesticide disposal.

This requirement will also eliminate this potential source of exposure in workers' homes. The rationale for the wording of this final requirement was discussed in Section VI.B.6 of this document.

In addition, as described in Section VI.C.6 of this PD 4, the Agency requires that registrants amend the labels of sodium pentachlorophenate labels to include the following information as stated in the Agency's PR Notice 83-3 (March 29, 1983):

> Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

8. Warnings about Eating, etc., during Application

Exposure/Risk: As previously stated, although the risks due to accidental ingestion of wood preservatives by smoking, drinking, or eating have not been quantified, the Agency determined that there is a potential for adverse human health effects in these exposure situations.

PD 2/3 Proposal: To eliminate risks from this potential exposure, the Agency proposed the following in the PD 2/3:

> Eating, drinking and smoking are prohibited during the application of pentachlorophenol to millwork, plywood, and particleboard.

Final Regulatory Position and Rationale: The Agency has determined that labels of pentachlorophenol formulatons for application on millwork and plywood, and particleboard must be amended to include the following information:

> Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

This requirement will greatly reduce or eliminate this type of accidental exposure during the application process. The rationale for the wording of this final requirement was discussed in Section VI.C.7 of this document.

9. Restricted Use

Exposure/Risk: The Agency was concerned that applicators untrained in the safe handling practices of pentachlorophenol for use on millwork and plywood, and particleboard could have a greater exposure than trained applicators due to misuse or carelessness. In order to reduce this potential exposure, the Agency proposed in the PD 2/3 to restrict use of this pesticide.

PD 2/3 Proposal: Specifically, the Agency proposed the following label modification:

> RESTRICTED USE PESTICIDE: For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

Final Regulatory Position and Rationale: The Agency has determined that in order for the benefits of use to exceed the risks, labels of pentachlorophenol for millwork and plywood, and particleboard uses must be amended to include the following information:

> RESTRICTED USE PESTICIDE: For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

This requirement is the same as that proposed in the PD 2/3. The Agency expects that this protective measure will reduce exposure to applicators by providing for training in safe use procedures.

VII. MEASURES TO REDUCE END-USER'S RISK FROM EXPOSURE TO PRESSURE-TREATED WOOD

The Agency believes that the majority of the population exposed to or using pesticide-treated wood is not aware that the wood is treated with a potentially hazardous pesticide and that individuals (including homeowners) need to be alerted to the potential hazards of using pesticide-treated wood. In the PD 2/3 several measures were considered for precautions concerning use of the treated wood. One was to require warnings on the label of the pesticide container itself. The Agency, however, has recognized that labeling information, in many instances, could not be expected to reach the consumer or purchaser of the commercially treated wood product, and in such circumstances the proposed pesticide label statements regarding treated-wood would not be useful.

The Agency also recommended in the PD 2/3 (pp. 719-721) the implementation of regulatory measures under Section 6 of TSCA to inform the end-user about treated wood. The PD 2/3 recommended promulgating a rule under TSCA to distribute labeling information to reduce the risks from the use of treated wood. TSCA Section 6(a)(3) provides that the Agency can require that products "be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of the activities." Promulgation of a rule under TSCA, however, could take several years to complete. The Agency wanted to develop a means of educating the public as soon as possible about the use of pesticide treated wood. Therefore, the Agency has explored other means of informing consumers of safe handling practices when using treated wood.

The wood preserving industry, as represented by the American Wood Preservers Institute (AWPI) and the Society of American Wood Preservers (SAWP), suggested an alternative approach, the Consumer Awareness Program (CAP), to inform the public about the proper use and handling of pressure-treated wood. In support of their suggestion, they submitted a detailed description of a CAP and a plan for its implementation (AWPI, Feb. 23, 1983). As part of their proposal, a Consumer Information Sheet (CIS) would be distributed with every purchase of pesticide-treated wood throughout the entire chain of commerce. These CIS's would be designed to alert the consumer and commercial users to the hazards and proper handling of wood products impregnated with wood preservatives.

The Agency believes a Consumer Awareness Program, such as that proposed by the industry, may be adequate to inform the users of treated wood of proper handling and use precautions. The CAP as proposed by the pressure-treatment industry representatives was intended to be completely voluntary. Because of the importance of the effective implementation of the CAP to the Agency's regulatory decision, however, EPA has determined that the program should be legally required as a condition of continued use of the wood preservatives for treating wood or wood products. Requiring the commercial producers of wood wood or wood products, which have been treated with wood preservatives, to participate in this effort to adequately inform the public of proper handling of treated wood will most effectively assure the program's successful implementation.

The Agency will require that wood treaters using pressure-treatment methods participate in a Consumer Awareness Program, but will not require participation of wood treaters using non-pressure treatment methods because the Agency does not expect use of wood commercially treated by non-pressure methods to pose an unreasonable risk to end-users.

First, the Agency expects that the pesticide residues on non-pressure treated wood will be low. For example, for millwork and plywood a 5% solution of pentachlorophenol is used for surface application (PD 2/3, pp. 523 and 524; for particleboard there is a 0.65% concentration (pentachlorophenol solids based on the oven-dried weight of the wood) in the wood-chip mixture; and sodium pentachlorophenate is applied to lumber and freshly peeled poles and posts at 6.3 to 6.9% for sapstain control (PD 2/3, p. 322, and p. 514). Thus, dermal or inhalation exposure to end-users is expected to be low during the handling or sawing/fabricating non-pressure treated wood.

Secondly, the patterns of use are such that exposure is also expected to be low. For example, treated millwork, plywood, and particleboard are not used in large amounts in residential interiors and are in some instances, sealed with paint or shellac, thus significantly reducing dermal and inhalation exposure (see Section V.H.3). While lumber treated with sodium pentachlorophenate could be used in interiors, the Agency expects dermal exposure to be low because of the low concentration used for treatment; inhalation exposure would be expected to be minimal because sodium pentachlorophenate is not highly volatile as is pentachlorophenol. The Agency did not propose in the PD 2/3 prohibiting interior used of wood treated for sapstain control (PD 2/3, p. 720).

Another potential use pattern, contact of pentachlorophenol-treated millwork and plywood and particleboard with domestic animals or food, feed, or water, was discussed in Section VI.H.4 of this PD 4. Sapstain-treated wood in contact with domestic animals or food, feed or water was discussed in Section VI.G.3 of this document. In summary, the Agency believes that exposure and risk for this use pattern are not significant.

Regarding proper disposal of non-pressure treated wood, the Agency believes not only that the concentration of pentachlorophenol or sodium pentachlorophenate residues will be low, but that consumers are unlikely to burn treated millwork and plywood and particleboard and wood treated for sapstain control in significant amounts.

In conclusion, upon consideration of the potential risks associated with the above uses of non-pressure-treated-wood, the Agency has determined that the risk potential to end-users of these non-pressure-treated wood items is probably low. Therefore, the Agency will not require that commercial wood treaters using non-pressure treatment methods participate in a Consumer

Awareness Program for the following non-pressure treated wood-end-products: millwood, plywood, particleboard, and wood treated for sapstain control. Should data be brought to the Agency's attention which might alter this conclusion, the Agency will act accordingly.

The risks associated with use of pressure-treated wood, however, compel the Agency to require that wood treaters using pressure treatment methods must participate in a Consumer Awareness Program to educate end-users of pressure-treated wood or pressure-treated wood items about safe handling and use procedures. To implement the Consumer Awareness Program, the Agency requires that, the registration of every product, which may be used for commercial pressure treatment of wood for distribution or sale and which contains either creosote, pentachlorophenol, or inorganic arsenic, must be amended to require the following statement to be prominently displayed on the label:

> This pesticide product may not be used for pressure-treatment of wood or wood products for sale or distribution unless the wood treater is participating in or affiliated with a program adequate to inform users of the treated wood of proper precautions to be taken in handling and using such treated wood.

At a minimum wood treaters must:

(1) distribute adequate consumer information sheets (CIS) with each shipment of pressure-treated wood so that at least one CIS will be securely attached to each bundle or batch of treated-wood as it leaves the treating plant;

(2) attach at least one CIS to each invoice for sale of pressure-treated wood;

(3) make available to retailers, wholesalers and distributors an adequate supply of CIS's and signs or placards to inform consumers of the existence of the CIS's; and

(4) encourage retailers to display signs or placards informing consumers of the availability of the CIS's and to make the CIS's readily available to the consumer.

The information which the United States Environmental Protection Agency requires to be included in the CIS is found in the attached labeling.

See Section VII. C. for the exact language required by EPA to be included in the Consumer Information Sheet for each of the three wood preservatives.

The Consumer Awareness Program can provide a reasonable approach to educating the public and alerting it to the proper precautions to be taken when handling treated wood. If the CAP is implemented and is effective in reducing risks, the Agency will not need to promulgate a rule pursuant to TSCA. TSCA rulemaking, however, remains a potential regulatory vehicle if the CAP program fails to meet the Agency's expectations or if it is not adequately implemented by distritutors of pressure-treated wood. In calculating the risks and benefits of continued registration of the wood preservatives, the Agency has assumed that an effective Consumer Awareness Program will be instituted. If such a program proves ineffective further regulating actions may be needed.

A. Elements of an Adequate Consumer Awareness Program

The issues which should be covered in an adequate Consumer Awareness Program are discussed below. Following this section is required language for Consumer Information Sheets for the three wood preservatives.

1. Use of Gloves

Exposure/Risk: Dermal exposure can result from contact with wood which has been treated with creosote, pentachlorophenol, or the inorganic arsenicals. Workers who handle (sawing and fabricating) the dry inorganic arsenical-treated wood have an estimated increase in potential risk of skin cancer, if not wearing gloves or other protective clothing, which ranges from 7.9×10^{-3} to 3.9×10^{-2} (PD 2/3, p. 217). The dermal absorption was assumed to be 0.01% (PD 2/3, pp. 199 and 205).

PD 2/3 Recommendation: In order to reduce dermal exposure through the hands, the Agency recommended in the PD 2/3 that the following statement be included on labeling information distributed with the treated wood to end-users:

> All individuals who handle pesticide-treated wood should wear gloves impervious to the wood preservatives (e.g., rubber).

This measure would apply to all construction workers, individuals installing fence posts, individuals climbing or working on utility poles, and other exposed individuals. If gloves were worn by workers who handle (sawing and fabricating) the dry inorganic arsenical-treated wood, the risk of skin cancer to an individual would be reduced from a range of 7.9×10^{-3} to 3.9×10^{-2} without gloves (PD 2/3, p. 217) to a range of 8.0×10^{-5} to 4.0×10^{-4} with gloves (PD 2/3, p. 699). This latter risk estimate (with gloves) included both dermal and inhalation exposure, but did not include the gastrointestinal exposure which may result from sawing inorganic arsenical-treated wood. The teratogenic and fetotoxic MOS for this activity would be increased from approximately 300 to 500 (PD 2/3, p. 699) by wearing gloves.

Although the dermal exposure to pentachlorophenol-treated wood and creosote-treated wood was not quantified, wearing gloves was estimated in the PD 2/3 to reduce hand dermal exposure by 99% and would be expected to result in a corresponding decrease in risk.

Final Agency Position and Rationale: New information on arsenic absorption submitted by AWPI (#36: 30000/28C) was reviewed by the Agency. Peoples (1979) studied the dermal absorption of arsenic in two dogs exposed to sawdust from wood treated with ammoniacal copper arsenate (ACA) or chromated copper arsenate (CCA) type C. One dog was exposed to 1.5 gm of ACA-treated Douglas fir sawdust containing 6.7% arsenate which was spread on a pad placed in intimate contact with the skin for 3 days. The second dog was exposed to 1.5 gm of CCA-C treated fine southern pine sawdust containing 3.0% pentavalent arsenic applied in the same manner for 2 days. Urine from each dog was collected for 2 days prior to treatment as well as after treatment and was analyzed for arsenate (As V), arsenite (As III), methyl arsente (MA) and dimethyl arsenate (DMA).

The Agency evaluated the results of this study and concluded that there was no evidence of arsenic dermal absorption from treated wood. Although only two dogs were used, the Agency believes the results are sufficient, in the absence of other data, to indicate that dermal absorption of arsenic from the treated wood does not occur (Zendzian, 1982).

New information on dermal exposure from pentachlorophenol pressure-treated wood was also submitted to the Agency (AWPI, Sept. 27, 1983). In a study performed for AWPI by Ingram and McGinnis at Mississippi State University, wood pressure-treated with pentachlorophenol in P-9 oil at 0.35 to 0.45 pounds per cubic foot was wiped with a cloth at 4.8 pounds pressure. The residue was then converted to pentachlorophenol residue per square foot. The Agency evaluated the results of this study and concluded that the upper-limit exposure was 500 micrograms per square foot (Day, June 18, 1984). Assuming the area of both hands to be 0.88 square feet, dermal contact with pentachlorophenol could result in a dermal exposure of 440 ug. Assuming a carpenter makes 25 hand contacts with the wood per day (for example, while building a deck for a home) for 5 days per week, 20 weeks per year, for 30 years, the margin of safety for teratogenic/fetotoxic effects from hand contact with pentachlorophenol pressure-treated wood is 1875 (Saito, June 19, 1984).

The potential oncogenic risk from hand dermal exposure to the HxCDD contaminant of pentachlorophenol in the wood is 8.8×10^{-4} (without gloves) assuming 15 ppm HxCDD and is 8.8×10^{-5} if gloves are worn. The potential oncogenic risk assuming 1 ppm HxCDD is 6.2×10^{-5} (without gloves) and is 6.2×10^{-6} if gloves are worn (Saito, June 19, 1984).

The Agency has concluded that gloves should be worn when handling wood which has been pressure-treated with pentachlorophenol.

No new information was received on dermal exposure from handling dry creosote-treated wood. The Agency assumes, as in the PD 2/3, that there is some risk to anyone handling wood treated with this wood preservative.

Based on the above information, the Agency has determined that, for inorganic arsenical-treated wood, end-users would not need to wear gloves, due to the negligible absorption rate demonstrated in the Peoples (1979) study (Zendzian, 1982). However, the model CIS contains statements acceptable to the Agency regarding gloves for handling pentachlorophenol-treated wood and creosote-treated wood. The statements are as follows:

> Avoid frequent or prolonged skin contact with pentachlorophenol-or creosote-treated wood; when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl-coated).

The Agency has concluded that this precautionary statement on the model CIS would inform the public about the necessary use of gloves when handling treated wood. Gloves are expected to reduce creosote and pentachlorophenol dermal exposure by 90% (Rispin April 24, 1984). The Agency will reevaluate the acceptability of the materials recommended for protective clothing for persons handling creosote-treated wood upon receipt of data from the registrants on permeability of materials in contact with creosote formulations.

2. Use of Coveralls, Gloves, and Dust Mask

Exposure/Risk: As discussed above, the Agency determined in the PD 2/3 that, during sawing operations with treated wood, preservative-bearing sawdust tends to become airborne with resultant inhalation, gastrointestinal, and widespread dermal exposure. During the sawing of inorganic arsenical-treated wood, the total oncogenic risk without protective clothing was estimated to range from 1.6×10^{-1} to 1.3×10^{-1} (PD 2/3, p. 217). The teratogenic/fetotoxic MOS for arsenically treated wood ranges from 106 to 128 (PD 2/3, p. 245). The creosote and pentachlorophenol risks have not been quantified.

PD 2/3 Recommendation: To reduce the exposure created from the sawing of pesticide-treated wood, the Agency recommended the following statements be included on labeling information to be distributed with the treated wood to end-users:

> Individuals who saw such wood occupationally should wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing (for homeowners, tightly-woven long sleeved cotton coveralls are acceptable). Individuals who saw pesticide treated wood and fabricate structures with treated wood should wear a dust mask capable of trapping 80% of particulates greater than 5 microns in size.

The Agency determined (PD 2/3) that implementation of this modification would reduce total dermal exposure to the wood preservatives by 80% if gloves and coveralls were worn, and inhalation exposure of particulates by 80% if a dust mask were worn by these workers. Wearing this protective clothing while working with inorganic arsenical-treated wood gives a total oncogenic risk range of 2.7×10^{-3} to 3.0×10^{-3} for persons who are occupationally exposed to sawdust from treated wood and a teratogenic/fetotoxic MOS of 3,520 (PD 2/3, pp. 650 and 654). The dermal absorption for inorganic arsenic from dry inorganic arsenic-treated wood was assumed to be 0.01% (PD 2/3, pp. 199 and 205).

Final Agency Position and Rationale: The Agency believes there is some risk to all persons handling and sawing treated wood. The model CIS addresses this concern and states:

> Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood wear a dust mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.
>
> Avoid frequent or prolonged skin contact with pentachlorophenol- or creosote-treated wood: when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl coated). When power sawing and machining, wear goggles to protect eyes from flying particles. Wash thoroughly after skin contact, and before eating, drinking, or use of tobacco products. If oily preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household clothing.

Although the risks from exposure to creosote and pentachlorophenol have not been quantified, this modification would reduce total dermal exposure to these preservatives by 80% if gloves and coveralls are worn, and inhalation exposure of particulates by 80% if a dust mask is worn by these workers (PD 2/3, p. 701). Wearing a dust mask while working with inorganic arsenical-treated wood would result in a potential inhalation risk of 1.7×10^{-4} for CCA and 4.2×10^{-4} for ACA. Wearing a dust mask would result in a potential risk of skin cancer from oral/gastrointestinal exposure of 6.2×10^{-5} for CCA and 1.5×10^{-4} for ACA (Rispin, April 18, 1984). Therefore, the Agency has concluded that dust masks should be worn by workers who saw arsenically treated wood. As mentioned above under the Section on "gloves," the Agency will reevaluate the acceptability of recommended materials upon receipt of the data submitted by the registrants.

3. Disposal of Treated Wood

Exposure/Risk: As stated in the PD 2/3 (p. 701), when creosote-treated wood is burned, various oncogenic or mutagenic compounds may be formed. When burned, wood treated with the inorganic arsenical compounds produces as a residue arsenic trioxide ash, a teratogen, mutagen and potent oncogen.

PD 2/3 Recommendation: To reduce exposure to the toxic products that may result from burning treated wood, the Agency recommended in the PD 2/3 that a prohibition against the burning of this wood be included in the labeling to be distributed with treated wood. Although the Agency believes there could be a significant hazard to human health from burning treated wood the hazard has not been quantified. However, implementation of this prohibition would eliminate exposure to the potential risks from burning pesticide-treated wood. Specifically, the PD 2/3 recommended:

> Treated wood should not be burned, but should be disposed of by methods, such as on-site burial, which are in accordance with local and state laws, and the Resource Conservation and Recovery Act.

Final Agency Position and Rationale: New information indicates that pentachlorophenol-treated wood, when burned, produces dioxins (including HxCDD) (Rappe and Marklund, 1978; and Jansson and Sundstrom, 1978). Therefore, based on the fact that additional toxic chemicals may be produced from burning treated wood, the Agency has included the following statement in the model Consumer Information Sheet:

> Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires, or in stoves or fireplaces because toxic chemicals may be produced in the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with State and Federal Regulations.

The latter statement would permit an effective, efficient method of disposing of large quantities of wood which may be commercially generated at, for example, large construction sites (e.g., for piers, homes with all-weather wood foundations).

This instruction would reduce improper disposal of pesticide-treated wood and would therefore reduce exposure and potential risks from burning pesticide-treated wood. Users would be informed that the treated wood should not be burned but be disposed of by placing in trash collection or by burial. The additional statement regarding burning in fireplaces and stoves, was added because it had been brought to the Agency's attention from several sources that some homeowners were burning treated wood in their home fireplaces and stoves.

The Agency believes that disposal of treated wood in this way will not pose unreasonable risks to human health and the environment, because the toxicants of concern are not likely to leach into the environment to any significant degree. Arsenate forms insoluble compounds in soil and is generally only moved by erosion. Arsenicals in treated wood have a very low tendency to leach into the soil, because the compound fixes well in the wood. Arsenic in water is adsorbed by sediments and becomes unavailable to aquatic plants or animals. (USDA, 1980, page xx, U.S. EPA, PD 1, p. 48448; Arsenault, 1975).

Pentachlorophenol degrades rapidly (within days) in the soil, given conditions of high moisture, temperature and organic matter. However, under sub-optimal soil conditions, or in the presence of a solvent or fungicide, pentachlorophenol degradation is slower (Day, 1980). Pentachlorophenol in its salt form (high pH conditions) is subject to leaching. Leaching or bleeding from pentachlorophenol-treated wood may result in low levels of pentachlorophenol contamination in the immediate vicinity (several inches) of the treated structure.

Creosote may be lost from treated wood by evaporation, exudation, or leaching, depending on the kind of coal used to make coal tar and other processing factors (U.S. EPA PD 1, p. 48159). While some of the lower distilling fractions are lost very soon after the wood is treated, the remainder is lost more slowly. Exuded liquid moves into soil a few inches before biodegradation. The fate of creosote in the environment is not known, but some components are rapidly biodegraded. Therefore, the Agency expects that disposal of treated wood by ordinary trash collection or by burial should not pose unreasonable adverse effects to man or the environment.

4. Indoor Use of Treated Wood

Exposure/Risk: The Agency concluded in the PD 2/3 that pesticide-treated wood which is destined for interior use or enclosed structures will result in inhalation and dermal exposure to the inhabitants of these dwellings or structures. The Agency determined in the PD 2/3 that the oncogenic risk to inhabitants in such enclosed areas from the interior uses (e.g., AWWF, plates and sills, and structural framing) of arsenically treated wood was 9×10^{-6} (PD 2/3, p. 217); the MOS was 128,200 (PD 2/3, p. 654). In enclosed areas treated with pentachlorophenol, inhalation exposures of about 8 ug/kg/day may occur as a result of the vaporization of pentachlorophenol. This exposure to pentachlorophenol results in a fetotoxic MOS of about 380; the exposure to HxCDD is negligible (low vapor pressure) (PD 2/3, pp. 337 and 693).

For occupational interior use of wood which has been pressure-treated with pentachlorophenol where there is poor ventilation, the exposure in occupational or commercial settings is 5.9 ug/kg/day (PD 2/3, p. 337). The oncogenic risk is negligible and the MOS is 510.

$$\left(\text{MOS} = \frac{\text{NOEL}}{\text{Exposure}} = \frac{3000\ \text{ug/kg/day}}{5.9\ \text{ug/kg/day}}\right)$$

If the occupational setting is well ventilated, the exposure is 0.38 ug/kg/day (PD 2/3, p. 337). The oncogenic risk is negligible and the MOS is 7,900. $\left(\frac{3000\ \text{ug/kg/day}}{0.38\ \text{ug/kg/day}}\right)$

Sodium pentachlorophenate, used for sapstain control, is a salt in an aqueous solution and thus has a very low vapor pressure. Consequently, risks from the use of 0.5% sodium pentachlorophenate for control of sapstain on wood which may be used indoors are not expected to be significant (PD 2/3, p. 694).

Although the Agency did not quantify the risks resulting from inhalation or dermal exposure to interior wood to which creosote has been applied, the Agency believes there is some degree of risk to individuals contacting creosote-treated wood dermally or breathing fumes in enclosed areas.

PD 2/3 Recommendation: To reduce these risks, the Agency recommended in the PD 2/3 limiting the use of pesticide-treated wood to exterior and specific indoor uses only. Under this limitation, treated wood which would ultimately be used in the interiors of human and animal dwellings would be limited to those posing a minimal risk.

Specifically, the Agency recommended (PD 2/3) the following statements be included on labeling information distributed with the treated wood to end-users:

> Treated wood should not be used indoors except for those support structures (e.g., foundation timbers, pole supports, and the bottom six inches of stall skirtboards) which are in contact with the soil in barns, stables and similar sites (all three wood preservatives); all weather wood foundations, sills and plates, structural framing (inorganic arsenicals only); millwork (pentachlorophenol only) which has outdoor surfaces (e.g., doorframes, windows, and patio frames); and wood treated for sapstain control with 0.5% sodium pentachlorophenate.

In addition to recommending that end-use labeling be distributed with the treated wood, the Agency also proposed in the PD 2/3 that similar prohibitions on interior uses of treated wood be enforced under FIFRA through appropriate statements on the label of the pesticide formulation. Implementation of this modification was expected to reduce the risk resulting from the use of treated wood in interior settings (e.g., paneling, cabinets, interior surfaces of log homes) by placing the responsibility on the treater not to treat wood intended for these uses.

Final Agency Position and Rationale: Reichold Chemicals Inc. recommended that a sealer be used on pentachloropenol pressure-treated wood used in interiors (Reichold, Aug. 3, 1981). USDA (1981) and AWPI (Comment #36: 30000/28C) provided data on the effectiveness of sealers to reduce vaporization of creosote and pentachlorophenol from commercially treated wood at 20°C and 31°C and a relative humidity of 50%. The air-flow rate was 1.0 liter per minute. Most sealers including stains, wood finishers, and varnishes were 70-100% effective in reducing these pesticide vapors with an average vapor reduction of 85% if two coats were applied (Day, December 9, 1983):

Also, as discussed in Section II, new information has convinced the Agency that the time a resident would spend in a home was overestimated in the PD 2/3. Instead of using the PD 2/3 estimate of 24 hours, the Agency revised the time spent to 15 hours (8 hours resting, 1 hour heavy work, and 6 hours of light work). Due to receipt of this new information, the Agency revised its exposure assumptions (Day, May 19, 1982 Exposure Analysis; Day, 1982 Rebuttal Analysis, and Day, Dec. 9, 1983), and, thus, its risk estimates.

USDA (1981) supplied data on the inhalation exposure resulting from the vaporization of pentachlorophenol from commercially dipped wood and aged pressure-treated wood (Day, 1982). The Agency had assumed (PD 2/3, p. 335) that the concentration of pentachlorophenol in the air from treated wood in residential interiors was 30 ug/m^3. The revised inhalation exposure levels are 4.8 - 20.4 ug/m^3 (industrially dip treated wood) and 0.5 - 10 ug/m^3 (aged treated wood) (Day, May 19, 1982 Exposure Analysis).

For wood intended for residential use which has been commercially dip/pressure-treated with pentachlorophenol and has an effective sealer applied, the fetotoxic MOS would range from 6,300 to greater than 10,000 (Van Ormer, 1982). The exposure to HxCDD would also be reduced by 85%. However, the Agency considered exposure to HxCDD to be negligible due to its lower vapor pressure relative to that of pentachlorophenol. The MOS range without sealers is 940-4000 (Van Ormer, 1982). If the commercial pentachlorophenol-treated wood is aged and a sealer is used, the fetotoxic MOS would be greater than 10,000 (Van Ormer, 1982).

For a well-ventilated occupational establishment with interiors consisting of pentachlorophenol dipped or pressure-treated wood, the fetotoxic MOS would range from 7,900 (if no sealer were used) to greater than 10,000 (if a sealer was used); in a poorly ventilated occupational setting, the MOS is 510 if no sealer is used and would range from 6,700 to greater than 10,000 if a sealer is used (Van Ormer, 1982).

Although the risks from interior uses of creosote-treated wood have not been quantified, the use of an effective sealer is assumed to reduce creosote vapors by 85% and thus contribute to a significant reduction in risk.

For wood pressure-treated with the inorganic arsenical compounds which may be used for some interior uses listed above (e.g., all-weather-wood-foundations or homes constructed with arsenic pressure-treated wood), the recalculated inhalation oncogenic risk to inhabitants of such an enclosed area without sealers is 4.6×10^{-6}. These risks are based on the new risk and exposure information discussed in Section II of this document and are not significantly different from background.

However, while it is true that sealers reduce vaporization of pentachlorophenol by about 85%, the Agency has received many reports of acute toxicity in enclosed areas where pentachlorophenol-treated wood has been used (Levin, #60:30000/28C; Friends of the Earth, #70:30000/28C; Center for Disease Control, #69:30000/28C; and U.S. EPA PIMS, 1981).

No data are available to indicate the length of time of effectiveness of the sealers; Levin (#60:30000/28C) submitted information which indicated that the wood preserving industry recommended continued air monitoring after sealing pentachlorophenol treated wood "to establish that any trace vapors remain at no-effect levels."

Also, AWPI (#36B;30000/28C, pp. 44) commented that in highly enclosed spaces pentachlorophenol should not be used to preserve a large portion of wall space and recommended use of pentachlorophenol-treated wood only for support structures and other building components subject to decay or termite hazards but only if appropriate sealer is applied.

Additional information submitted by the California Department of Health Services to the Agency (Jackson and Stratton, #87:30000/28C) indicated that occupants of an office building containing sealed pentachlorophenol pressure-treated wood in Long Beach, California, continued to have increased levels of free pentachlorophenol in their urine compared to the levels prior to occupancy. Air levels of pentachlorophenol were 50 ug/m^3) prior to sealing the wood. Air levels in this range (40 - 50 ug/m^3) were reported to be associated with acute toxic effects by Jackson and Stratton (#87:30000/28c). After sealing the wood, air levels decreased to 5 ug/m^3, a level not known to be associated with any direct adverse health effects (#87:30000/28c).

While sealers may provide an adequate Margin of Safety from potential teratogenic/fetotoxic effects, in light of the information on acute toxic effects the Agency has incorporated statements into the model CIS to discourage use of pentachlorophenol-treated wood unnecessarily indoors, including interiors of residences, and industrial and commercial buildings. The Agency has also incorporated statements in the CIS regarding limitations on interior use of creosote-treated wood and wood treated with the inorganic arsenicals. The CIS states:

> Pentachlorophenol-treated wood should not be used in residential, industrial, or commercial interiors except for laminated beams or building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.
>
> Creosote-treated wood should not be used in residential interiors. Creosote-treated wood in interiors of industrial buildings should only be used for wood-block flooring and industrial building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.
>
> Coal tar pitch and coal tar pitch emulsion are effective sealers for creosote-treated wood-block flooring. Urethane, epoxy, and shellac are acceptable sealers for all creosote-treated wood. Urethane, shellac, latex epoxy enamel, and varnish are acceptable sealers for pentachlorophenol-treated wood.

The Agency will not advise against the interior use of arsenical - treated wood, because the risks of use (4.6×10^{-6}) have been shown not to be above background. The arsenic air levels measured in homes constructed with arsenic treated wood are not significantly different from background arsenic air levels when all dust is vacuumed from the wood surfaces (Koppers, Nov. 15, 1983).

Therefore, the Agency will require that the CIS contain in the following statement:

> Exposed wood pressure-treated with waterborne arsenical preservatives may be used inside residences as long as all dust is vacuumed from the wood surface.

The Agency expects that the Consumer Awareness Program, when initiated by the wood preserving industry, will adequately inform users as to the proper use of pressure-treated wood. Based on the revised risks of the sealed treated wood for interior uses, the Agency believes that limited interior uses of sealed pentachlorophenol and creosote treated wood will not cause unreasonable adverse effects to man or the environment. See Appendix B for a comparison of the risks calculated in the PD 2/3 and the present recalculated risks.

As stated above, the Agency had also proposed in the PD 2/3 that similar prohibitions on interior uses of treated wood be stated on the labels of the pesticide formulation and be enforced under FIFRA. The responsibility would have been placed on the wood treater not to treat wood intended for use in interiors. However, the Agency now recognizes that the treatment plant applicator would not necessarily know how the treated wood might later be used. Thus, it would be unreasonable to hold the treater responsible for a use occurring after treatment. Therefore, the Agency will not require that such label restrictions be stated on pesticide formulations which are used by applicators who treat wood for commercial distribution.

5. Animals/Food/Feed/Water Issue

Exposure/Risk: The Agency expressed concern in the the PD 2/3 that pesticide-treated wood could come into contact with food, feed, and water resulting in some exposure to domestic animals and/or humans.

PD 2/3 Recommendation: To eliminate this route of exposure, the Agency recommended that certain labeling information accompany the treated wood. The recommended statement to be included on the label was as follows:

> Treated wood should not be used in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins, and watering troughs).

The Agency also proposed in the PD 2/3 that these prohibitions be enforced under FIFRA through appropriate statements on the label of the pesticide fomulation. This regulatory action would place the responsibility on the wood treater not to treat wood intended for those uses. The Agency now recognizes that the treatment plant operator does not necessarily know how the treated wood will be used. Therefore, it would be inappropriate to hold the treater responsible for a later use, and this label change will not be implemented.

Final Agency Position and Rationale: AWPI (Feb. 9, 1982) and USDA (1981) objected to this recommended prohibition, stating that it was too wide-ranging and that very little contamination, if any, would be expected.

Animal Contact

A report by USDA (1980) has indicated that several types of domestic animals can be exposed to the pesticides in treated wood from breathing air containing pesticide vapors or pesticide-laden dust particles, from oral contact, or from dermal contact. The principal problem is chemical residues in food products of animal origin which humans may consume rather than acute toxicity in animals following direct exposure, though some toxicity has been reported.

Cattle, for example, can come into contact with pentachlorophenol by breathing vapors or dust in a barn constructed in part from poles and boards treated with pentachlorophenol or by licking or chewing on treated wood. Horses may crib (bite) treated wood and thereby may ingest pesticides from treated wood. Deaths in piglets and skin burns on the sow's udder have been reported when sows are farrowed (give birth) on pentachlorophenol-treated wood that is bleeding (oozing pesticide). Problems with poultry have been reported when sawdust/wood chips containing pentachlorophenol are used for bedding (litter) (USDA, 1980, and FDA, 1983).

Pentachlorophenol and HxCDD residues have been shown to accumulate in the milk and blood of cows fed technical pentachlorophenol (Firestone, 1979). Dioxin residues have been shown to accumulate in the meat and tissues of cattle fed technical grade pentachlorophenol with the largest HxCDD residue of 3 ppb being found in the liver (Zabik, 1980). A USDA meat/poultry sampling showed pentachlorophenol residues in animals, with the highest concentration of 2 ppm in hogs (Day, 1983). USDA (1980) also reports that pentachlorophenol residues in blood of dairy cattle which have been housed in a barn containing a feedbunk made of pentachlorophenol-treated wood are higher (0.279 mg/liter) than residues in the blood of dairy cattle housed without a pentachlorophenol treated feedbunk (0.050 mg/liter).

Based on the above information, the Agency believes it would be prudent to prohibit the use of pentachlorophenol-treated wood in interiors of farm buildings where it may come into contact with domestic animals or livestock which may crib or lick the wood, in order to prevent any potential toxicity to the animals or to humans who may consume food products of animal origin.

Though the Agency has no data on creosote residues in the tissues of domestic animals following exposure, the Agency believes it is prudent to prohibit the use of creosote-treated wood in interiors of farm buildings where the treated wood may come into contact with domestic animals or livestock which may crib or lick the wood.

Regarding arsenic, studies have shown that arsenic is readily excreted in cattle and does not biomagnify through the food chain and that dermal absorption of arsenic from treated wood is negligible (Day, 1983; Zendzian, 1982; ; NIOSH, 1983; and PD2/3, p. 170). If domestic animals do crib or lick the wood, exposure is expected to be limited (USDA, 1980). Therefore, the Agency will not require a statement in the CIS regarding direct contact of domestic animals with arsenic-treated wood. However, as stated below under "Food and Feed," FDA has the responsibility for setting food additive regulations where pesticides may contaminate food or animal feed; e.g., where the food or animal feed is in contact with pesticide-treated wood.

The Agency requires that the following statements be contained in the CIS:

> Do not use pentachlorophenol or creosote treated wood for farrowing or brooding facilities. Wood treated with pentachlorophenol or creosote should not be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood. In interiors of farm buildings where domestic animals or livestock are unlikely to crib or lick the wood, pentachlorophenol or creosote treated wood may be used for building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.
>
> Urethane, epoxy, and shellac are acceptable sealers for all creosote-treated wood. Urethane, shellac, latex epoxy enamel, and varnish are acceptable sealers for pentachlorophenol-treated wood.

Food and Feed

The Food and Drug Administration (FDA) has the responsibility for setting food additive regulations. FDA has stated that preserved wood cannot be used under circumstances where the pesticide may become a component of food or feed unless a food additive regulation has been promulgated and prescribes safe use (Hile, Aug. 4, 1983).

FDA has issued a regulation for the safe use of pentachlorophenol and sodium pentachlorophenate on wooden articles at levels up to 50 ppm in wood contacting raw agricultural products (21 CFR 178.3800). However, FDA has expressed concern about the use of pentachlorophenol-treated wood under other conditions where the pentachlorophenol would be likely to migrate to other food or animal feed, such as silage, because chlorinated phenols or their contaminants could become concentrated in the edible tissue of animals (Hile, Aug. 4, 1983). No food additive regulation permits pentachlorophenol, creosote or inorganic arsenicals from treated wood in food or animal feed. Therefore, any food or animal feed which contain residues from contact with treated wood will be adulterated under the Food, Drug and Cosmetic Act. Accordingly, the EPA requires that the following statement be included in the CIS to provide guidance to the consumer who may be considering using the treated wood where it may contact food or animal feed:

> Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

The Agency believes that it would also be prudent to include the following statement in the model CIS:

> Do not use treated wood for cutting boards or counter tops.

Drinking Water (Human)

The use of treated wood in drinking water systems includes interiors of reservoir roofs, support beams, and truss structures above water levels, and may involve either direct or indirect contact with drinking water. In both situations migration of preservative chemicals at significant rates is possible, by leaching when direct contact is involved and via condensation and other mechanisms when treated wood is in indirect contact with drinking water.

Arsenic: The Agency believes that arsenic-treated wood should not be used in contact with drinking water until studies are conducted to show that the contribution of arsenic to drinking water via this source cannot be expected to exceed 5.0 ppb in the water. This limit for arsenic is 10% of the Maximum Contaminant Limit (MCL) of 50 ppb established under the National Interim Primary Drinking Water Regulations (40 Federal Register, 59566, December 24, 1975). A 10% contribution limit of any given MCL or of a given Suggested No-Adverse-Effect Level (SNARL), when no MCL exists, has been suggested by the National Academy of Sciences (NAS) Committee on Water Treatment Chemicals

(NAS, 1982) for intentional water quality degradation by a given impurity in a water treatment chemical. As the intentional degradation during water treatment is no different than degradation occurring during water storage, (e.g., from contact with treated wood,) a 10% MCL contribution limit is appropriate in both situations.

Creosote: Because components in creosote have been shown to be oncogenic and mutagenic (PD 2/3) and because creosote and other coal tar based products impart an objectionable taste and odor to water, the Agency recommends that creosote-treated wood not be used where it may come in contact with drinking water. The World Health Organization (1983) has recently recommended against the use of coal tar-based and associated materials in drinking water contact.

Pentachlorophenol: Drinking water SNARL values for pentachlorophenol have been calculated by the NAS assuming contributions from drinking water ranging from 0-20%. Considering a conservative hypothetical situation where water contributes as much as 20% of the total intake of pentachlorophenol, the NAS SNARL for drinking water would be 0.021 ppm. With the NAS recommended 10% contribution limit discussed above for arsenic, the acceptable level for pentachlorophenol present in drinking water due to contact with pentachlorophenol-treated wood would be 0.0021 ppm. In a study submitted by the wood preservative industry, levels of pentachlorophenol in water which was in contact with pentachlorophenol treated wood were significantly higher (4.2 and 4.7 ppm) (AWPI, 1983). Therefore, the Agency will recommend that the CIS contain statements indicating that pentachlorophenol-treated wood should not be used where it may come in contact with drinking water, except for docks and bridges constructed from pentachlorophenol-treated wood.

The statement which the Agency requires be included in the Consumer Information Sheet regarding pesticide-treated wood coming into contact with drinking water is as follows:

> Pesticide-treated wood should not be used where it may come into direct or indirect contact with public drinking water except for uses involving incidental contact such as docks and bridges.

Drinking Water (Domestic Animals)

In order to determine whether wood preservatives migrate in water which comes into contact with certain structures built of pressure-treated wood, AWPI (1983) performed a study using water troughs made of arsenic, pentachlorophenol, and creosote pressure-treated wood. Pesticide residues in the water in these structures were measured with samples taken (1) from an area adjacent to the treated wood and (2) from the center of the structure.

Arsenic: The Agency reviewed the results of this study (Day, 1983). It was found that, though arsenic was recovered from the water at levels as high as 40 ppb, the residues were below the 50 ppb upper limit for arsenic set by EPA's National Interim Primary Drinking Water Regulations (40 FR 59566, Dec. 24, 1975). It is also below the 0.2 ppm (200 ppb) upper limit recommended by NAS for domestic animal drinking water (NAS, 1972, p. 310).

Therefore, the Agency has concluded that arsenic-treated wood could be used for construction of containers for water for domestic animal or livestock consumption.

Pentachlorophenol: The results of the study also showed transfer of pentachlorophenol from the wood to the water, with the pentachlorophenol (4.2 ppm) distributed homogeneously throughout. Normal city water contains up to 0.0001 ppm pentachlorophenol (PD 2/3, p. 341); therefore, domestic animals could receive up to 42,000 times the normal intake of pentachlorophenol due to direct contact of the water with the treated wood (Day, Jan. 18, 1983). This could contribute to the pentachlorophenol levels found in livers of domestic animals (PD 2/3, p.343). Therefore, the Agency will require that pentachlorophenol treated wood should not be used where it may come into direct contact with drinking water for domestic animals and livestock.

Creosote: The water in contact with the creosote-treated wood showed homogeneous contamination of creosote at 0.1 ppm. Because of the diverse nature of creosote and the uncertainty of the significance of 0.1 ppm in water, it is not possible to define these results in terms of hazard. However, the World Health Organization, in its 1983 proposal entitled "Guidelines for Drinking Water Quality," has recommended discontinuation of the use of coal tar-based and associated materials in contact with public drinking water (WHO, 1983).

Creosote and other coal tar-based products have been shown to be mutagenic and oncogenic (PD 2/3) and can also impart an objectionable taste and odor to water. The Agency believes, therefore, that it would not be prudent to allow creosote-treated wood to come into direct contact with drinking water for domestic animals and livestock.

To summarize, the Agency has concluded that inorganic arsenic (CCA salt or oxide) treated wood can be used in direct contact with drinking water for domestic animals, but pentachlorophenol and creosote treated wood cannot.

The Agency requires that the CIS contain the following statement:

> Do not use pentachlorophenol or creosote treated wood where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

6. Outdoor Uses of Pressure-Treated Wood

In the PD 2/3, possible exposures from patios, decks and walkways were not considered. However, these potential exposures are now addressed in the CIS. The statement in the CIS is:

> Only treated wood that is visibly clean and free of surface residue should be used for patios, decks and walkways.

The Agency has no monitoring data on exposure of persons to arsenically-treated playground equipment or persons who inadvertently contact arsenically-treated wood surfaces such as handrails, sun decks, park benches, stadium seats, and boardwalks. As discussed previously in Section VII.A.1 of this document, dermal absorption of inorganic arsenic from dry treated wood is considered to be negligible (Zendzian, 1982). The dermal absorption of arsenic from treated wood which subsequently becomes wet with water is 0.1% (Day, Oct. 27, 1983). The dermal absorption of pentachlorophenol from dry pentachlorophenol treated wood or from pentachlorophenol-treated wood which subsequently becomes wet with water is 1.0% (Day, Oct. 27, 1983). There are no data on dermal absorption of creosote from creosote-treated wood, but the Agency assumes that some absorption does occur.

Therefore, in order to reduce exposure to pentachlorophenol and creosote treated wood, the CIS will state the following:

> Wood treated with pentachlorophenol or creosote should not be used where it will be in frequent or prolonged contact with bare skin (for example, chairs and other outdoor furniture), unless an effective sealer has been applied.

7. Use of Treated Wood for Beehives and Hive Platforms

AWPI (Feb. 24, 1983) suggested that a statement be included in the CIS informing users of treated wood that only acid copper chromate (ACC) and chromated zinc chloride (CZC)-treated wood should be used in the construction of beehives and hive platforms because creosote, pentachlorophenol, or arsenically treated wood are acutely toxic to bees. No data were submitted to substantiate this claim. This use had not been considered in the PD 2/3 and no other comments were received on this subject.

The Agency has researched this issue and has found that pentachlorophenol is recommended widely as a preservative for hive stands and bottom boards of hives (Ludvik, 1984). No data to support AWPI's claims of toxicity to bees from using treated wood for beehives were found.

However, the Agency believes it would be prudent to caution users of treated wood against using the treated wood in those parts of beehives which are likely to come into contact with the honey and possibly result in pesticide residues in the honey.

The Agency requires that the following statement be included in the CIS:

> Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

B. Model Consumer Awareness Program

AWPI and SAWP developed a model Consumer Awareness Program (CAP) and a model Consumer Information Sheet (CIS) containing use site precautions and safe working practices which EPA has reviewed and has found to be generally satisfactory to address its concerns. EPA, however, requires that other statements be included in the model CIS. The CIS would serve as the main vehicle for conveying information about treated wood to purchasers of landscape ties, fence posts, lumber and timber. The focus of the CAP would be on ensuring the dissemination of the CIS at the time of sale or delivery to these end-users.

Each wood treater will be able to customize its CIS. Thus, the individual wood treater's CIS at a minimum, would contain in one section the information included in the model CIS, in so far as it applies to the wood preserver's product, but might also include in a separate section information not contradictory to the statements required by EPA. Such additional information might include the sealer's name, address and logo. Additional warnings may also be added. In all cases, however, the use site precautions and the safe handling practices information required by EPA would have to be distinct and clearly legible, using Bodoni bold 12 pt type.

The wood treater will have primary responsibility for ensuring that the CIS is disseminated to the consuming public. Wood treaters are expected to distribute CIS's and signs or placards to their retailers, wholesalers and distributors, attach a CIS to each bundle or batch of treated wood, and attach a CIS to each invoice. The preservative manufacturers, formulators and trade associations may also work to ensure the consumer receives the necessary product information.

A yearly survey of member compliance and effectiveness of the distribution of the CIS will be conducted by EPA.

The CAP must be implemented when the amended labels for the wood preservatives appear on the market approximately 6 months to 1 year after the Notice concluding the Wood Preservatives RPAR is published in the Federal Register.

The obligation to implement an adequate Consumer Awareness Program is on wood treaters who use wood preservatives to commercially pressure-treat wood. To fulfill this obligation they must:

(1) distribute adequate consumer information sheets (CIS) with each shipment of pressure-treated wood so that at least one CIS will be securely attached to each bundle or batch of treated wood as it leaves the treating plant;

(2) attach at least one CIS to each invoice for sale of pressure-treated wood;

(3) make available to retailers, wholesalers and distributors an adequate supply of CIS's and signs or placards to inform consumers of the existence of the CIS's; and

(4) encourage retailers to display signs or placards informing consumers of the availability of the CIS's and to make the CIS's readily available to the consumer.

Although only the users of the wood preservatives are actually required by the label instructions to implement the Consumer Awareness Program, EPA expects the other organizations may participate as well.

Such additional organizations include the wood preserving industry trade associations and the registrants of the affected wood preservative products. These organizations may be able to implement parts of the program more economically and efficiently by, for example, printng Consumer Informaton Sheets in bulk for distribution or by serving as a centralized clearinghouse for encouraging distributors and retailers of treated wood to fully implement the CAP. Two wood preservative trade associations, the Society of American Wood Preservers and the American Wood Preservers Institute, have submitted to EPA a plan for implementing the CAP (36J:30000/28C). In this plan the wood treaters, the trade associations and the registrants would work together to attempt to assure the program is effective. EPA has reviewed this plan and has found it to be a wholly satisfactory means of carrying out the label requirement and encouraging the industry to fully implement it. The ultimate obligation to carry out an adequate program to inform the public, however, lies with users of the wood preservatives as a condition of their legal use of the products.

C. Consumer Information Sheets

1. CREOSOTE

The following is the wording acceptable to EPA for the Consumer Information Sheet (CIS) for creosote pressure-treated wood. This CIS is based on the version proposed by AWPI and SAWP (Feb. 24, 1983), but it has been revised to reflect additional Agency concerns. These Consumer Information Sheets must accompany each shipment of creosote pressure-treated wood.

CONSUMER INFORMATION SHEET

This wood has been preserved by pressure treatment with an EPA-registered pesticide containing creosote to protect it from insect attack and decay. Wood treated with creosote should be used only where such protection is important.

Creosote penetrates deeply into and remains in the pressure-treated wood for a long time. Exposure to creosote may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use the treated wood.

USE SITE PRECAUTIONS FOR CREOSOTE PRESSURE-TREATED WOOD

-- Wood treated with creosote should not be used where it will be in frequent or prolonged contact with bare skin (for example, chairs and other outdoor furniture) unless an effective sealer has been applied.

-- Creosote-treated wood should not be used in residential interiors. Creosote-treated wood in interiors of industrial buildings should only be used for wood-block flooring and industrial building components which are in ground contact and are subject to decay or insect infestation, and where two coats of an appropriate sealer are applied.

-- Wood treated with creosote should not be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood.

-- In interiors of farm buildings where domestic animals or livestock are unlikely to crib (bite) or lick the wood, creosote-treated wood may be used for building components which are in ground contact and are subject to decay or insect infestation and where two coats of an effective sealer are applied.

-- Do not use creosote treated wood for farrowing or brooding facilities.

-- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

-- Do not use treated wood for cutting boards or countertops.

-- Only treated wood that is visibly clean and free of surface residues should be used for patios, decks and walkways.

-- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

-- Creosote-treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

-- Do not use creosote-treated wood where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS FOR CREOSOTE PRESSURE-TREATED WOOD

-- Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

-- Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dusk mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

-- Avoid frequent or prolonged skin contact with creosote-treated wood; when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl-coated).

-- When power-sawing and machining, wear goggles to protect eyes from flying particles.

-- Wash exposed areas thoroughly after skin contact, and before eating, drinking or use of tobacco products.

-- If oily preservatives or sawdust accumulates on clothes, launder before reuse. Wash work clothes separately from other household clothing.

-- Coal tar pitch and coal tar pitch emulsion are effective sealers for creosote-treated wood block flooring. Urethane, epoxy, and shellac are acceptable sealers for all creosote-treated wood.

2. PENTACHLOROPHENOL

The following is the wording required for the Consumer Information Sheets (CIS) which must accompany each shipment of pentachlorophenol pressure-treated wood.

CONSUMER INFORMATION SHEET

This wood has been preserved by treatment with an EPA-registered pesticide containing pentachlorophenol, to protect it from insect attack and decay. Wood treated with pentachlorophenol should be used only where such protection is important.

Pentachlorophenol penetrates deeply into and remains in the pressure-treated wood for a long time. Exposure to pentachlorophenol may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use the treated wood.

USE SITE PRECAUTIONS FOR PENTACHLOROPHENOL PRESSURE-TREATED WOOD

-- Wood treated with pentachlorophenol should not be used where it will be in frequent or prolonged contact with bare skin (for example, chairs and other outdoor furniture), unless an effective sealer has been applied.

-- Pentachlorophenol-treated wood should not be used in residential, industrial, or commercial interiors except for laminated beams or building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.

-- Wood treated with pentachlorophenol should not be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood.

-- In interiors of farm buildings where domestic animals or livestock are unlikely to crib (bite) or lick the wood, pentachlorophenol-treated wood may be used for building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.

-- Do not use pentachlorophenol-treated wood for farrowing or brooding facilities.

-- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

-- Do not use treated wood for cutting boards or countertops.

-- Only treated wood that is visibly clean and free of surface residue should be used for patios, decks and walkways.

-- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

-- Pentachlorophenol-treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

-- Do not use pentachlorophenol-treated wood where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS FOR PENTACHLOROPHENOL PRESSURE-TREATED WOOD

-- Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

-- Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dusk mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

-- Avoid frequent or prolonged skin contact with pentachlorophenol-treated wood; when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl-coated).

-- When power-sawing and machining, wear goggles to protect eyes from flying particles.

-- Wash exposed areas thoroughly after skin contact, and before eating, drinking or use of tobacco products.

-- If oily preservatives or sawdust accumulates on clothes, launder before reuse. Wash work clothes separately from other household clothing.

-- Urethane, shellac, latex epoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

3. INORGANIC ARSENICALS

The following is the wording required for the Consumer Information Sheets (CIS) which must accompany each shipment of inorganic arsenical pressure-treated wood.

CONSUMER INFORMATION SHEET

This wood has been preserved by treatment with an EPA-registered pesticide containing inorganic arsenic to protect it from insect attack and decay. Wood treated with inorganic arsenic should be used only where such protection is important.

Inorganic arsenic penetrates deeply into and remain in the pressure-treated wood for a long time. Exposure to inorganic arsenic may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use the treated wood.

USE SITE PRECAUTIONS FOR INORGANIC ARSENICAL PRESSURE-TREATED WOOD

-- Exposed wood pressure treated with waterborne arsenical preservatives may be used inside residences as long as all dust is vacummed from the wood surface.

-- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

-- Do not use treated wood for cutting boards or countertops.

-- Only treated wood that is visibly clean and free of surface residue should be used for patios, decks and walkways.

-- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

-- Treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS FOR INORGANIC ARSENICAL PRESSURE-TREATED WOOD

-- Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

-- Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dusk mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

-- When power-sawing and machining, wear goggles to protect eyes from flying particles.

-- Wash exposed areas thoroughly after skin contact, and before eating, drinking or use of tobacco products.

-- If preservatives or sawdust accumulates on clothes, launder before reuse. Wash work clothes separately from other household clothing.

VIII. MODIFICATIONS TO THE TERMS AND CONDITIONS OF REGISTRATION OF WOOD PRESERVATIVE PRODUCTS [1]

A. Upper Limits for Hexachlorodibenzo-p-dioxin (HxCDD) Contamination

In order to avoid cancellation, registrants of the wood preserving chemicals technical pentachlorophenol and pentachlorophenol salts must meet the following requirements within 30 days of publication of the Final Notice of Determination concluding the Wood Preservatives RPAR or within 30 days of receipt of such Notice, whichever occurs later:

1. File an application to amend the Confidential Statements of Formula (CSF) for products containing technical pentachlorophenol or its salts to indicate that the HxCDD contamination does not exceed 15 ppm, and that 2,3,7,8-TCDD is below the limits of detection using a gas chromatography-mass spectrophotometry method acceptable to the Agency (e.g., Buser and Bosshardt, 1976).

2. File an application to amend the Confidential Statements of Formula for products containing technical pentachlorophenol or its salts to indicate that, effective 18 months after publication of the Notice or receipt by the registrant (whichever occurs later), the HxCDD contamination does not exceed 1.0 ppm. (The method used to lower HxCDD levels to 15 ppm or 1.0 ppm or lower must not increase the hexachlorobenzene or the chlorinated dibenzofuran levels above those in products marketed at the time of publication of the FR Notice.)

B. Label Modifications

In order to avoid cancellation, registrants of the wood preserving chemicals (inorganic arsenicals, pentachlorophenol and pentachlorophenol salts, and creosote) must file an amended application to modify the terms and conditions of registration to include certain information on their product labels.

The amended application must be filed within 30 days after publication of the Final Notice of Determination concluding the Wood Preservative RPAR or within 30 days of receipt of such Notice, whichever occurs later.

The labels must be amended for the various uses of the wood preserving chemicals to include the following information.

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[1] The worker protection requirements specified in this document are established pursuant to FIFRA, which provides no means of regulating occupational safety and health hazards except insofar as they are directly associated with the use of a registered pesticide. EPA has made no attempt to regulate any workplace hazard except those associated with the use of pesticide products containing creosote, pentachlorophenol (and its salts) and the inorganic arsenicals as wood preservatives. EPA in developing these worker protection requirements has only considered the hazards directly attributed to the use of these pesticides.

1. All uses of pentachlorophenol or pentachlorophenol salts

- The U.S. EPA has determined that pentachlorophenol can produce defects in the offspring of laboratory animals. Exposure to pentachlorophenol during pregnancy should be avoided.

2. All creosote, pentachlorophenol and inorganic arsenical products which are used for the commercial pressure-treatment of wood

This pesticide product may not be used for treatment of wood or wood products for sale or distribution unless the wood treater is participating in or affiliated with a program adequate to inform users of the treated wood of proper precautions to be taken in handling and using such treated wood.

At a minimum wood treaters must:

a. distribute adequate consumer information sheets (CIS) with each shipment of pressure-treated wood so that at least one CIS will be securely attached to each bundle or batch of treated wood as it leaves the treating plant;

b. attach at least one CIS to each invoice for sale of pressure-treated wood;

c. make available to retailers, wholesalers and distributors an adequate supply of CIS's and signs or placards to inform consumers of the existence of the CIS's; and

d. encourage retailers to display signs or placards informing consumers or the availability of the CIS's and to make the CIS's readily available to the consumers.

The information which the United States Environmental Protection Agency requires to be included in the CIS is found in the attached labeling.

3. Pressure Treatment Uses for Inorganic Arsenicals

a. Restricted Use Pesticide:

For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.

b. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors).*

c. Applicators who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing (including overall, jacket, gloves and boots) impervious to the wood treatment formulation.* In addition, employees who enter pressure-treatment cylinders must wear properly fitting, well-maintained, high efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10 ug/m^3) averaged over an 8-hour work period. Air monitoring programs, procedures and record retention and submission must be conducted in accordance with the instructions on the attached labeling material.

d. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with State and Federal regulations.

e. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

f. Applicators must not eat, drink, or use tobacco products during those parts of the application process that may expose them to the wood treatment formulation (e.g., manually opening/closing cylinder doors, moving trams out of cylinders, mixing chemicals, and handling freshly treated wood).

g. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

h. A closed emptying and mixing system must be used for all powder formulations of the inorganic arsenicals. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

i. Processes used to apply inorganic arsenical formulations shall leave no visible surface deposits on the wood, as defined by AWPA Standard C-1 and AWPB Standards LP2 and LP22. (Visible surface deposits means a surface residue or crystallization on the treated wood. Small isolated or infrequent spots or chemical on otherwise clean wood shall be allowed.)

j. Employees in the work area of an arsenical wood treatment plant must wear properly fitting, well-maintained high efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10 ug/m3) averaged over an 8-hour work period. Air monitoring programs, procedures and record retention and submission must be conducted in accordance with the instruction on the attached labeling material.

*Note to user: Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinylchloride (PVC), neoprene, NBR (Buna-N), rubber and polyethylene.

ATTACHED LABELING

IMPLEMENTATION - Each arsenical wood treatment plant employer shall require all employees potentially exposed to airborne inorganic arsenic to wear properly fitting, well maintained high efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic for the entire period that the employees are in the treatment application work area or engaged in any activity associated with the treatment process. Alternatively, to potentially relieve employees from the burden of wearing respirators, the employer may implement a Permissible Exposure Limit (PEL) monitoring program.

All wood treatment plant employers who elect to implement the PEL monitoring program must determine the current levels of airborne arsenic, averaged over an 8-hour period, to which their employees are exposed. Monitoring data obtained one year prior to this implementation date may be used to determine the initial levels of airborne exposure to employees, if the data were obtained in the same manner as described below in the "Monitoring and Measurements Procedures" section, and if the employer can certify that no changes have been made since the time of monitoring that could have resulted in new or additional employee exposure to inorganic arsenic including events on the PEL Checklist (see PEL Checklist, below).

If the initial or subsequent monitoring demonstrates that airborne inorganic arsenic in a work area is greater than 10 ug/m3, all employees working in that area are required to wear properly fitting, well maintained high efficiency filter respirators MSHA/NIOSH approved for inorganic arsenic. If in subsequent monitoring, at least two consecutive measurements taken at least seven (7) days apart, the inorganic arsenic levels are below 10 ug/m3, employees in those areas may discontinue the wearing of the respirators, except as discussed in the section "PEL Checklist" below. However, if the employee exposure is above 5 ug/m3 and below 10 ug/m3, the employer shall repeat monitoring at least every six months until at least two consecutive measurements, taken at least seven days apart, are below 5 ug/m3. The employer may then discontinue monitoring, except as discussed in the section "PEL Checklist" (below).

If the monitoring reveals employees are exposed to airborne arsenic levels below 5 ug/m3, monitoring need not be repeated, except as discussed in the section "PEL Checklist" (below).

PEL CHECKLIST - In all cases where there has been a change in production, process, control, or employee handling procedures, or if any events in the PEL Checklist occurred, or if for any other reason an employer should suspect new or additional airborne inorganic arsenic, additional monitoring that complies with the requirements for initial monitoring shall be completed. Responses to the Checklist will become part of the monitoring records. Monitoring is required within 2 months if any of the following events/questions on the check list can be answered in the affirmative with respect to any events which may have occurred since the last monitoring report submitted to the Agency:

1. After the wood has been treated, have you changed from hand stacking to mechanical stacking or from mechanical stacking to hand stacking? If yes, when?

2. Has your production capacity increased significantly? If yes, when?

3. Have you changed from a ready-to-use or dilute concentrate to a mix-it-yourself formulation? Has the proportional amount of arsenic in the solution increased, e.g., have you shifted from CCA type A or C to type B? If yes, when?

4. Has a significant, i.e., reportable under the "Comprehensive Environmental Response, Compensation, and Liability Act of 1980" (Superfund), 42 U.S.C. 9601 et seq., spill occurred? If yes, when?

5. Is treated wood being retained on the drip pad for less time? If yes, when?

6. Have there been any other production, process, control or employee handling procedure changes which could result in new or additional airbone inorganic arsenic? Identify change, and when it occurred.

MONITORING AND MEASUREMENT PROCEDURES - The employer shall collect personal air samples, including at least one sample which is adequate to represent typical conditions for a full work shift (at least 7 hours) for each job classification in each work area. Sampling should be done using a personal sampling pump calibrated at a flow rate of 2 liters per minute. Samples should be collected on 0.8 micrometer pore size membrane flter (37 mm diameter). The method of sampling analysis should have an accuracy of not less than ±25% (with a confidence limit of 95%) for 10 micrograms per cubic meter of air (10 ug/m^3) and ± 35% (with a confidence limit of 95%) for concentrations of inorganic arsenic between 5 and 10 ug/m^3.

Monitoring may be conducted through a request made to the Occupational Safety and Health Administration (OSHA) for monitoring assistance which may be provided free of charge under the terms of the OSHA consultation program as provided under Section 7(c)(1) of the OSHA Act, or by employees or contractors of the employer's choosing.

The Environmental Protection Agency (EPA) may direct that remonitoring take place at statistically selected establishments to assure that the Checklist is effective in identifying events which increase airborne arsenic. Selected employers will be notified by EPA/State enforcement representatives. The employer will be responsible for obtaining current air monitoring data within the time specified in the remonitoring notification and for submitting these data and reports to the EPA as described below.

DATA SUBMISSION AND CERTIFICATION - The employer shall establish and maintain accurate records which include responses to the PEL Checklist and all monitoring reports. The annual records or copies thereof shall be submitted to the

U.S. Environmental Protection Agency
Office of Pesticides and Toxic Substances
Compliance Monitoring Staff (EN-342)
401 M Street, SW.
Washington, D.C. 20460

All records submitted will be certified by the employer as accurate and in compliance with all calibration, analytical and sampling requirements outlined in this program. If the employer received assistance from an OSHA 7(c)(1) consultant, that consultant's report to the employer will be an acceptable record of calibration, analysis, and monitoring requiring no additional certification.

CONSUMER INFORMATION SHEET

This wood has been preserved by treatment with an EPA-registered pesticide containing inorganic arsenic to protect it from insect attack and decay. Wood treated with inorganic arsenic should be used only where such protection is important.

Inorganic arsenic penetrates deeply into and remains in the pressure-treated wood for a long time. Exposure to inorganic arsenic may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use the treated wood.

USE SITE PRECAUTIONS FOR INORGANIC ARSENICAL PRESSURE-TREATED WOOD

-- Exposed wood pressure - treated with waterborne arsenical preservatives may be used inside residences as long as all dust is vacuumed from the wood surface.

-- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

-- Do not use treated wood for cutting boards or countertops.

-- Only treated wood that is visibly clean and free of surface residue should be used for patios, decks and walkways.

-- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

-- Treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS FOR INORGANIC ARSENICAL PRESSURE-TREATED WOOD

-- Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

-- Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dusk musk. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

-- When power-sawing and machining, wear goggles to protect eyes from flying particles.

-- Wash exposed areas thoroughly after skin contact, and before eating, drinking or use of tobacco products.

-- If preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household clothing.

4. Pressure Treatment Uses for Creosote

a. Restricted Use Pesticide:

For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification.

b. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact with creosote is expected (e.g., handling freshly treated wood and manually opening cylinder doors).*

c. Applicators who manually open cylinder doors must wear gloves and a respirator.*

d. Applicators who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment formulation (e.g., cylinders that are in operation or are not free of the treatment formulation) must wear protective clothing (including overalls, jacket, gloves and boots) impervious to the wood treatment formulation and a respirator.*

e. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

f. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

g. Applicators must not eat, drink, or use tobacco products during those parts of the application process that may expose them to the wood treatment formulation (e.g., manually opening/closing cylinder doors, moving trams out of cylinders, mixing chemicals, and handling freshly treated wood).

h. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

*NOTE TO USER:

Respirators acceptable for use by applicators of creosote must be properly fitting, well-maintained, half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for polynuclear aromatics and organic vapors. Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of creosote are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N).

CONSUMER INFORMATION SHEET

This wood has been preserved by pressure treatment with an EPA-registered pesticide containing creosote to protect it from insect attack and decay. Wood treated with creosote should be used only where such protection is important.

Creosote penetrates deeply into and remains in the pressure-treated wood for a long time. Exposure to creosote may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use the treated wood.

USE SITE PRECAUTIONS FOR CREOSOTE PRESSURE-TREATED WOOD

-- Wood treated with creosote should not be used where it will be in frequent or prolonged contact with bare skin (for example, chairs and other outdoor furniture), unless an effective sealer has been applied.

-- Creososte-treated wood should not be used in residential interiors. Creosote-treated wood in interiors of industrial buildings should only be used for wood-block flooring and industrial building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.

-- Wood treated with creosote should not be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood.

-- In interiors of farm buildings where domestic animals or livestock are unlikely to crib (bite) or lick the wood, creosote-treated wood may be used for building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.

-- Do not use creosote-treated wood for farrowing or brooding facilities.

-- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

-- Do not use treated wood for cutting boards or countertops.

-- Only treated wood that is visibly clean and free of surface residues should be used for patios, decks, and walkways.

-- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

-- Creosote-treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

-- Do not use creosote-treated wood where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS FOR CREOSOTE PRESSURE-TREATED WOOD

-- Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

-- Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dusk mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

-- Avoid frequent or prolonged skin contact with creosote-treated wood; when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl-coated).

-- When power-sawing and machining, wear goggles to protect eyes from flying particles.

-- Wash exposed areas thoroughly after skin contact, and before eating, drinking or use of tobacco products.

-- If oily preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household clothing.

-- Coal tar pitch and coal tar pitch emulsion are effective sealers for creosote-treated wood-block flooring. Urethane, epoxy, and shellac are acceptable sealers for all creosote-treated wood.

5. Pressure Treatment Uses for Pentachlorophenol

a. Restricted Use: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification.

b. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors).*

c. Applicators who manually open cylinder doors must wear gloves and a respirator.*

d. Applicators who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment formulation (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing (including overalls, jacket, gloves and boots) impervious to the wood treatment formulation and a respirator.*

e. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

f. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and workshoes or boots and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

g. Applicators must not eat, drink, or use tobacco products during those parts of the application process that may expose them to the wood treatment formulation (e.g., manually opening/closing cylinder doors, moving trams out of cylinders, mixing chemicals, and handling freshly treated wood).

h. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

i. Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls) must be worn when emptying and mixing prilled or flaked formulations of pentachlorophenol. After September 1, 1987, a closed system must be used when emptying and mixing prilled or flaked formulations of pentachlorophenol. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

*NOTE TO USER:

Respirators acceptable for use by applicators of pentachlorophenol must be properly fitting, well-maintained, half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors and acid gases.

Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile. In addition, plastic-coated disposable coveralls impervious to dust are acceptable for dust protection.

CONSUMER INFORMATION SHEET

This wood has been preserved by treatment with an EPA-registered pesticide, containing pentachlorophenol, to protect it from insect attack and decay. Wood treated with pentachlorophenol should be used only where such protection is important.

Pentachlorophenol penetrates deeply into and remains in the pressure-treated wood for a long time. Exposure to pentachlorophenol may present certain hazards. Therefore, the following precautions should be taken both when handling the treated wood and in determining where to use the treated wood.

USE SITE PRECAUTIONS FOR PENTACHLOROPHENOL PRESSURE-TREATED WOOD

-- Wood treated with pentachlorophenol should not be used where it will be in frequent or prolonged contact with bare skin (for example, chairs and other outdoor furniture), unless an effective sealer has been applied.

-- Pentachlorophenol-treated wood should not be used in residential, industrial, or commercial interiors except for laminated beams or building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.

-- Wood treated with pentachlorophenol should not be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood.

-- In interiors of farm buildings where domestic animals or livestock are unlikely to crib (bite) or lick the wood, pentachlorophenol-treated wood may be used for building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.

-- Do not use pentachlorophenol-treated wood for farrowing or brooding facilities.

-- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

-- Do not use treated wood for cutting boards or countertops.

-- Only treated wood that is visibly clean and free of surface residue should be used for patios, decks and walkways.

-- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey.

-- Pentachlorophenol-treated wood should not be used where it may come into direct or indirect contact with public drinking water, except for uses involving incidental contact such as docks and bridges.

-- Do not use pentachlorophenol-treated wood where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

HANDLING PRECAUTIONS FOR PENTACHLOROPHENOL PRESSURE-TREATED WOOD

-- Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

-- Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dusk mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations of airborne sawdust from treated wood.

-- Avoid frequent or prolonged skin contact with pentachlorophenol-treated wood; when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl-coated).

-- When power-sawing and machining, wear goggles to protect eyes from flying particles.

-- Wash exposed areas thoroughly after skin contact, and before eating, drinking or use of tobacco products.

-- If oily preservatives or sawdust accumulates on clothes, launder before reuse. Wash work clothes separately from other household clothing.

-- Urethane, shellac, latex epoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

6. Groundline Treatment of Poles with Creosote and Pentachlorophenol

a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicators' certification.

b. Applicators must wear gloves impervious to the wood treatment formulations (e.g., polyvinyl acetate, polyvinyl chloride or neoprene) in all situations where dermal contact is expected (e.g., during the actual application process and when handling freshly treated wood).*

c. Applicators must wear disposable coveralls (e.g., nitrile or neoprene for creosote; nitrile or polyethylene for pentachlorophenol) or other suitable impermeable protective clothing during the application and mixing processes and all situations where dermal contact is expected.

d. Protective clothing must be changed when it shows signs of contamination. Launder non-disposable protective clothing separately from other household clothing. Dispose of worn-out protective clothing and workshoes or boots in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

e. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional office for guidance.

f. Applicators must not eat, drink, or use tobacco products during those parts of the application process that may directly expose them to the wood treatment formulation.

g. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products or using restrooms.

7. Home and Farm Uses (Including Railroad Tie Repair) of Creosote-Restricted Use

a. RESTRICTED USE PESTICIDE: For sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicators' certification.

b. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (for example, during the actual application process and when handling freshly treated wood).

c. Spray applicators must wear protective clothing (including overalls, jackets, gloves and boots) impervious to the wood treatment formulation, and a respirator,* head covering, and goggles when spraying.

d. Applicators who apply creosote by other application processes (e.g., brush-on) must wear disposable coveralls or other suitable impermeable protective clothing.* Launder non-disposable protective clothing separately from other clothing.

e. Protective clothing must be changed when it shows signs of contamination. Dispose of worn-out protective clothing and workshoes or boots in a general landfill, in the trash, or in any other manner approved for pesticide disposal.

f. For products for farm use or for railroad tie repair farm use: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

For household domestic use products: Securely wrap original pesticide container in several layers of newspaper and discard in the trash. Do not reuse empty container.

g. Applicators must not eat, drink, or use tobacco products those parts of the application process that may expose them to the treatment formulation.

h. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

i. Avoid inhaling vapors. If inhalation of vapors cannot be avoided, applicators must wear a properly fitting, well-maintained half-mask canister or cartridge respirator which is MSHA/ NIOSH - approved for polynuclear aromatics and organic vapors.

j. Do not apply where there may be direct contact with domestic animals or livestock, and where there may be contamination of food, feed, or drinking and irrigation water.

k. Do not apply in interiors. Do not apply to wood intended for use in interiors except for those support structures which are in contact with the soil in barns, stables, and similar sites and which are subject to decay or insect infestation. Interior surfaces of the treated wood should be sealed with two coats of an appropriate sealer.

l. Do not apply creosote to wood intended for farrowing or brooding facilities. Do not apply creosote to wood intended to be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood. Creosote may be used to treat wood intended to be used in interiors of farm buildings where domestic animals or livestock are unlikely to crib or lick the wood, if two coats of an appropriate sealer will be applied.

m. Do not apply wood intended to be used in a manner in which the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

n. Do not use this product to treat wood intended to be used for cutting boards or counter tops.

o. Do not use this product to treat wood intened for construction of those portions of beehives which may come into contact with the honey.

p. Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with public drinking water, except for those uses involving incidential contact such as docks and bridges.

q. Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

r. Wood to be treated with this product should be cut to size before treatment. If it is necessary to saw or machine wood after treatment, wear goggles to protect the eyes from flying particles and a dust mask to avoid inhaling sawdust from the treated wood. If oily preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household laundry.

s. Contact with treated surfaces should be avoided even after the preservative has dried. When handling treated wood wear tighly woven coveralls and gloves which are impervious (e.g., vinyl coated) to the pesticide. Wash exposed skin thoroughly after contact with treated wood and before eating, drinking or using tobacco products.

t. Wood which has been treated with this product should be disposed of by burial or ordinary trash collection. Do not burn treated wood in an outdoor fire or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes.

u. This product should not be used to treat wood which will be in frequent or prolonged contact with skin, unless the wood will be treated with an effective sealer.

*NOTE TO USER:

Respirators acceptable for use by applicators of creosote must be properly fitting, well-maintained, half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for polynuclear aromatics and organic vapors.

Examples of acceptable materials for protective clothing (e.g., gloves, overalls, head covering, jackets, and boots) required during application and handling of creosote are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N). In addition to these materials, nitrile is also acceptable for disposable coveralls.

Urethane, exoxy, and shellac are acceptable sealers for all creosote-treated wood.

8. Home and Farm Uses (Including Railroad Tie Repair) of Pentachlorophenol (Restricted Use)

   a. RESTRICTED USE PESTICIDE: For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicators' certification.

   b. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (for example, during the actual application process and when handling freshly treated wood).

c. Spray applicators must wear protective clothing (including overalls, jackets, gloves and boots) impervious to the wood treatment formulation, and a respirator, head covering, and goggles when spraying.*

d. Applicators who apply pentachlorophenol by other application methods (e.g., brush-on) must wear disposable coveralls or other suitable impermeable protective clothing.* Launder non-disposable protective clothing separately from other clothing.

e. Protective clothing must be changed when it shows signs of contamination. Dispose of worn-out protective clothing and work-shoes or boots in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

f. For products for farm use or railroad tie repair: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

For household/domestic use products: Securely wrap original pesticide container in several layers of newspaper and discard in the trash. Do not use empty container.

g. Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation.

h. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

i. Avoid inhaling vapors. If inhalation of vapors cannot be avoided, applicators must wear a properly fitting, well-maintained half-mask cannister or cartridge respirator which is MSHA/NIOSH approved for organic vapors and acid gases.

j. Do not apply where there may be direct contact with domestic animals or livestock, and where there may be contamination of food, feed, or drinking and irrigation water.

k. Do not apply in interiors. Do not apply to wood intended for use in interiors except for those support structures which are in contact with the soil in barns, stables, and similar sites and which are subject to decay or insect infestation; and millwork which has outdoor surfaces (e.g., doorframes, windows and patio frames). Interior surfaces of the treated wood should be sealed with two coats of an appropriate sealer.

l. Do not apply pentachlorophenol to wood intended for farrowing or brooding facilities. Do not apply pentachlorophenol to wood intended to be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood. Pentachlorophenol may be used to treat wood intended to be used in interiors of farm buildings where domestic animals or livestock are unlikely to crib or lick the wood, if two coats of an appropriate sealer will be applied.

m. Do not apply to wood intended to be used in a manner in which the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food.

n. Do not use this product to treat wood intended to be used for cutting boards or counter tops.

o. Do not use this product to treat wood intended for construction of those portions of beehives which may come into contact with the honey.

p. Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with public drinking water, except for those uses involving incidental contact such as docks and bridges.

q. Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

r. Wood to be treated with this product should be cut to size before treatment. If it is necessary to saw or machine wood after treatment, wear goggles to protect the eyes from flying particles and a dust mask to avoid inhaling sawdust from the treated wood. If oily preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household laundry.

s. Contact with treated surfaces should be avoided even after the preservative has dried. When handling treated wood wear tightly woven coveralls and gloves which are impervious (e.g., vinyl coated) to the pesticide. Wash exposed skin thoroughly after contact with treated wood, and before eating, drinking or using tobacco products.

t. Wood which has been treated with this product should be disposed by burial or ordinary trash collection. Do not burn treated wood in an outdoor fire or in stoves or fireplaces because toxic chemicals may be produced as part of the smoke and ashes.

u. This product should not be used to treat wood which will be in frequent or prolonged contact with skin, unless the wood will be treated with an effective sealer.

*NOTE TO USER:

Respirators acceptable for use by applicators of pentachlorophenol must be properly fitting, well-maintained half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors and acid gases.

Examples of acceptable materials for protective clothing (e.g., overalls, jackets, head covering, boots, disposable coveralls, and gloves) required during application and handling of pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile. Urethane, shellac, latex epoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

9. Brush-On Treatments of Inorganic Arsenicals (Unclassified Use)

a. Applicators must wear gloves (e.g., rubber, vinyl or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood).

b. Applicators must wear disposable coveralls (e.g., vinyl or polyethylene) or other similar impermeable clothing during the application process where dermal contact is expected.

c. Applicators must not eat, drink, or use tobacco products during those parts of the application process that may directly expose them to the treatment solution.

d. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

e. Protective clothing must be changed when it shows signs of contamination. Launder non-disposable protective clothing separately from other household clothing. Dispose of worn-out protective clothing in a manner approved for pesticide disposal and in accordance with State and Federal regulations.

f. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

g. For application to the cut ends of pressure-treated wood only. Do not dilute or mix with other products.

h. For commercial construction use only. Not for household use.

10. Sapstain Use of Sodium Pentachlorophenol Salts

a. RESTRICTED USE PESTICIDE: For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

b. All applicators must wear gloves* impervious to the wood treatment formulation in all situations where dermal contact is expected (for example, during the application process and when handling freshly treated wood).

c. Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls) must be worn when emptying and mixing powder formulations of pentachlorophenate. After September 1, 1987, a closed system must be used when emptying and mixing powder for formulations of pentachlorophenate. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

d. For the spray method of application: spray apparatus must (1) be operated so as to minimize overspray (i.e., no visible mist) and (2) be free of leaks in the system. Should there be a visible mist, spray applicators in the vicinity of the apparatus (the zone in which the mist is visible) must wear a respirator* and protective clothing (including overalls, jackets, boots, head covering impervious to the wood treatment formulation, and goggles).*

e. Individuals who enter, clean, or repair vats, tanks or other related equipment that is contaminated with the treatment solution must wear a respirator. In addition, where dermal contact is expected, these individuals must wear overalls, jackets, boots, head covering impervious to the wood treatment formulation and goggles.*

f. Protective clothing must be changed when it shows signs of contamination. Applicators must leave all protective clothing, workshoes or boots, and equipment at the plant. Worn-out protective clothing, and workshoes or boots, must be left at the plant and disposed of in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

g. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

h. Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation.

i. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

***NOTE TO USER:**

Respirators acceptable for use by applicators of sodium pentachlorophenate must be properly fitting, well-maintained half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors.

Examples of acceptable materials for protective clothing (e.g., overalls, jackets, head covering, boots, disposable coveralls, and gloves) required during application and handling of sodium pentachlorophenate are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N), and nitrile.

11. Non-Pressure Treatment Plant Dip/Flow and Spray Uses of Pentachlorophenol

a. RESTRICTED USE PESTICIDE: For sale to and use only by certifed applicators or persons under their direct supervision and only for those uses covered by the certifed applicator's certification.

b. Applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (for example, during the application process and when handling freshly treated wood).*

c. Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls) must be worn when emptying and mixing prilled or flaked formulations of pentachlorophenol. After September 1, 1987, a closed system must be used when emptying and mixing prilled or flaked formulations of pentachlorophenol. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.

d. For the spray method of application: spray apparatus must (1) be operated so as to minimize overspray (i.e., no visible mist) and (2) be free of leaks in the system. Should there be a visible mist, spray applicators in the vicinity of the apparatus (the zone in which the mist is visible) must wear a respirator* and protective clothing (including overalls, jackets, boots, head covering impervious to the wood treatment formulation, and goggles).*

e. Individuals who enter, clean, or repair vats, tanks or other related equipment that are contaminated with the treatment solution must wear a respirator. In addition, where dermal contact is expected, these individuals must wear overalls, jackets, boots, head covering impervious to the wood treatment formulation and goggles.*

f. Protective clothing must be changed when it shows signs of contamination. Applicators must leave all protective clothing, workshoes or boots, and equipment at the plant. Worn-out protective clothing, and workshoes or boots, must be left at the plant and disposed of in any general landfill, in the trash, or in any other manner approved for pesticide disposal.

g. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use accoring to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

h. Applicators should not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation.

i. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.

j. Do not apply to logs which are intended for use in construction of log homes.

*NOTE TO THE USER:

Respirators acceptable for use by applicators of pentachlorophenol must be properly fitting, well-maintained half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for organic vapors and acid gases. Examples of acceptable materials for protective clothing (e.g., overalls, jackets, head covering, boots, disposable coveralls, and gloves) required during application and handling of pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N), and nitrile. In addition, plastic-coated disposable coveralls impervious to dust are acceptable for dust protection.

C. Data Requirements.

In an action separate from this PD4, registrants will be required to submit certain data within 90 days after notification to maintain existing registrations in effect pursuant to FIFRA Section 3(c)(2)(B).

1. Registrants of products containing technical pentachlorophenol or its salts will be required to submit the following:

   a. A description of the starting materials, manufacturing process and reaction conditions including any steps to reduce HxCDD.

   b. Information on product identity relative to identification of ingredients, statement of composition and a discussion of the formation of impurities.

c. Data on the analysis and certification of product ingredients relative to preliminary analysis, certification of limits, and analytical methods for the enforcement of limits. An analytical method employing combined gas chromatography and mass spectrophatometry is acceptable (e.g., Buser and Bosshardt, 1976).

d. HxCDD analyses every three months, the first analysis to be submitted within the stated 90 day period.

e. A description of any changes in the manufacturing process used to lower HxCDD to 15 ppm and/or 1.0 ppm or lower must also be submitted within the stated time period of 90 days. The methods used to lower HxCDD must not increase the chlorinated dibenzofurans and HCB contaminants above the levels in products marketed at the time of publication of the FR Notice.

f. Information on the technical feasibility and costs of reducing HxCDD contamination further than the 1.0 ppm upper limit.

2. Registrants of creosote will be required to submit the following:

   a. Epidemiology study on workers at creosote treatment plants.

   b. Air monitoring and dermal exposure data from creosote treatment plants.

3. Registrants of creosote and arsenic will be required to submit the following:

   a. Data on permeability of glove and protective clothing materials indicating degree of protection for creosote and inorganic arsenical formulations.

4. Registrants of bis (tri-n-butyltin) oxide, copper-8-quinolinolate, copper-naphthenate, acid copper chromate, chromated zinc chloride, sodium tetrachlorophenate, zinc naphthenate 3-iodo-2-propynyl butylcarbamate, and barium metaborate will be required to submit the following:

   a. Chronic feeding studies

   b. Oncogenicity studies

   c. Reproduction studies

   d. Teratology studies

5. Registrants of pentachlorophenol will be required to submit dermal and inhalation exposure data on the home and farm spray application of pentachlorophenol.

Comments on the PD 2/3 and April 14, 1983 Public Meeting

Allied Chemical, Morristown, NJ. July 21, 1983. 79(30000/28C)

American Institute of Timber Construction, Englewood, CO. April 9, 1981. 10(30000/28C)

American Wood Preservers Institute, Mclean, VA. May 20, 1981. 36A(30000/28C)

American Wood Preservers Institute, McLean, VA. and National Forest Products Association, Washington, D.C. May 20, 1981. 36B(30000/28C)

American Wood Preservers Institute, McLean, VA. May 20, 1981. 36C(30000/28C)

American Wood Preservers Institute, Mclean, VA. c/o Steptoe and Johnson, Washington, D.C. May 29, 1981. 36D(30000/28C)

American Wood Preservers Institute, McLean, VA. c/o Steptoe and Johnson Washington, D.C. June 10, 1981. 36E(30000/28C)

American Wood Preservers Institute, McLean, VA. and National Forest Products Association, Washington, D.C. c/o Steptoe and Johnson, June 12, 1981. 36F(30000/28C)

American Wood Preservers Institute, McLean, VA, c/o Steptoe and Johnson, Washington, D.C. August 31, 1981. 36G(30000/28C)

American Wood Perservers Institute, McLean, VA. February 9, 1982. 36H(30000/28C)

American Wood Perservers Institute, Society of American Wood Preservers, Inc., and National Forest Products Association. February 15, 1982. 36I(30000/28C)

American Wood Perservers Institute, Society of American Wood Preservers, Inc. National Forest Products Association. February 24, 1983. 36J(30000/28C)

American Wood Preservers Institute, McLean, VA. July 14, 1983. 78(30000/28C)

American Wood Preservers Institute, McLean, VA. August 23, 1983. 81(30000/28C)

American Wood Preservers Institute, McLean, VA. November 14, 1983. 84(30000/28c)

American Wood Preservers Institute, McLean, VA. Jan. 30, 1984. 86(30000/28C)

American Wood Preservers Institute, Vienna, Va. March 21, 1984. 88(30000/28C)

Arneson Timber Company, Steeville, MO. May 15, 1981. 46(30000/28C)

Association of American Railroads, Washington, DC. May 20, 1981. 34(30000/28C)

Association of American Railroads, Washington, DC. June 24, 1981. 71(30000/28C)

Burdell, Charles, A., Spartanburg, SC. September 6, 1983. 82(30000/28C)

C.A. Niece Company, Lambertville, N.J. April 24, 1981. 19(30000/28C)

California Division of Occupational Safety and Health, April 25, 1983.
San Francisco, CA. 67(30000/28C)

Carson's Hardware, Hellertown, PA. May 12, 1981. 29(30000/28C)

Ceder Fence Distributors Company, Inc., Greenbrook, N.J. April 16, 1981.
9(30000/28C)

Center for Disease Control, Public Health Service, Atlanta, GA. May, 1983.
69(30000/28C)

Consumers Power Company, Jackson, MI. May 14, 1981. 31(30000/28C)

Coopers Creek Chemical Corporation, West Conshohocken, PA. April 6, 1981.
4(30000/28C)

Department of the Army, Kingsport, TN. March 5, 1981. 1(30000/28C)

Detroit Edison, Detroit, MI. May 18, 1981. 40(30000/28C)

Dow Chemical Company, Midland, NJ. May 15, 1981. 32(3000/28C)

Doylestown Lumber and Millwork, Doylestown, PA. April 22, 1981. 18(30000/28C)

Dries Building Supply Co., Macungie, PA. April 20, 1981. 11(30000/28C)

Ecological and Speciality Products, Paterson, NJ. May 12, 1981.
47(30000/28C)

Edison Electric Institute, Washington, DC. May 20. 1981. 35(30000/28C)

Friends of the Earth, Washington, DC. June 30, 1981. 55(30000/28C)

Friends of the Earth, Washington, DC. May 11, 1983. 64(30000/28C)

Friends of the Earth, Washington, DC. May 19, 1983. 70(30000/28C)

GAF Supply Center, Baltimore, MD. May 5, 1981. 21(30000/28C)

Georgia Department of Agriculture, Atlanta, GA. May 5, 1983. 62(30000/28C)

Gibson-Homans Company, Twinsburg, OH. April 2, 1981. 3(3000/28C)

G.M., Deck & Sons, Amber, PA. May 18, 1981. 45(30000/28C)

Good-Life, Inc., Effingham, IL. April 17, 1981. 58(30000/28C)

Hatboro Lumber & Fuel Co., Hatboro, PA. April 21, 1981. 16(30000/28C)

Health Research Group, Washington, DC. May 4, 1983. 65(30000/28C)

Herric & Smith, c/o Samuel Cabot Inc., Washington, DC. May 22, 1981. 38(30000/28C)

Illinois Power Co., Decatur, IL. April 6, 1981. 5(30000/28C)

International Woodworkers of America, Local 38, Shelton, WA. May 12, 1983. 63(30000/28C)

International Woodworkers of America, Portland, OR. April 29, 1983. 68(30000/28C)

Iowa-Illinois Gas & Electric Co., Davenport, IA. June 4, 1981. 50(30000/28C)

J.H. Baxter & Co., San Mateo, CA. July 11, 1983. 76(30000/28C)

James Haggis & Sons, Malden, MA. May 6, 1981. 57(30000/28C)

Jenison-Wright Corporation, Toledo, OH. May 15, 1981. 37(30000/28C)

Kerr-McGee Company, Oklahoma City, OK. May 15, 1981. 33(30000/28C)

Koppers Company, Pittsburgh, PA. July 13, 1983. 72(30000/28C)

Koppers Company, Pittsburgh, PA. July 13, 1983. 77(30000/28C)

Koppers Company, Pittsburgh, PA. December 12, 1983. 85(30000/28C)

Koppers Company, Pittsburgh, PA. November 15, 1983. 89(30000/28C)

Levin, H., University of California, May 9, 1983. 60(30000/28C)

Lloyd H. Daub, Inc., Bridgeport, PA. April 16, 1981. 15(30000/28C)

Louisiana-Pacific Corp., Red Bluff, CA. May 17, 1981. 43(30000/28C)

Louisiana-Pacific Corp., Samoa, CA. July 7, 1983. 73(30000/28C)

McFarland Cascade, Sandpoint, ID. July 6, 1983. 74(30000/28C)

McPhillips Manufacturing Co., Mobile, AL. June 3, 1981. 49(30000/28C)

Michlin Chemical Corporation, Detroit, MI. May 8, 1981. 25(30000/28C)

Michlin Chemical Corporation, Detroit, MI. May 5, 1981. 25A(30000/28C)

Missouri Department of Agriculture, May, 18, 1981. 25A(30000/28C)

Missouri Forest Products Assoc., Jefferson City, MO. May 19, 1981. 39(30000/28C)

Monona Grove Clinic, Madison, WI. May 11, 1981. 27(30000/28C)

Monsey Products, Kimberton, PA. May 7, 1981. 23(30000/28C)

National Forest Products Association, Washington, DC. July 11, 1983. 75(30000/28C)

National Paint Center, Lansdale, PA. April 15, 1981. 7(30000/28C)

National Solvent Corporation, Medina, OH. April 10, 1981. 6(30000/28C)

National Woodworks, Inc., Birmingham, AL. May 6, 1981. 24(30000/28C)

Nebraska Cooperative Extension Service, Lincoln, NE. June 12, 1981. 51(30000/28C).

N.Y. Power Pool, Schenectady, NY. May 20, 1981. 30(30000/28C)

Niagara Mohawk Power Corp, Syracuse, NY. May 20, 1981. 42(30000/28C)

OSMOSE, Buffalo, NY. May 18, 1981. 41(30000/28C)

OSMOSE, Buffalo, NY, April 27, 1983. 61(30000/28C)

Philadelphia Reserve Supply Company, Croyden, PA. April 24, 1981. (17:30000/28C)

Portland Cement Association, Skokie, IL. May 4, 1981. 26(30000/28C)

Portland Cement Association, Skokie, IL. May 6, 1983. 66(30000/28C)

Publishers Paper, Oregon City, OR. June 23, 1981. 54(30000/28C)

RAECO Products, Rochester, NY. April 30, 1981. 22(30000/28C)

Reichold Chemicals, Inc. and Vulcan Materials Company, c/o Paul Hastings, Janofsky and Walker, Washington, DC. June 3, 1983. 83(30000/28C)

Reliance Company, Brood Brook, CT. May 15, 1981. 59(30000/28C)

Roberts Consolidated Industries, Kalamazoo, MI. April 24, 1981. 20(30000/28C)

Sampson Paint Manufacturing Company, Inc., Richmond, VA. April 16, 1981. 12(30000/28C)

Sentinel Wood Treating, Inc., Ashland, MO. March 18, 1981. 2(30000/28C)

Seymour Chemicals Inc., Bannockburn, IL. June 3, 1981. 52(30000/28C)

Society of American Wood Preservatives, Arlington, VA. June 15, 1981. 53(30000/28C)

Soult Wholesales Company, Clearfield, PA. April 16, 1981. 8(30000/28C)

Standard Concrete Company, York, PA. April 15, 1981. 13(30000/28C)

State of California, Department of Health Services. October 19, 1983. 87(30000/28C)

Structural Wood Systems, Greenville, AL. April 17, 1981. 14(30000/28C)

U.S. Department of Energy, Washington, DC. May 20, 1981. 44(30000/28C)

Walpole Woodworkers, Walpole, MA. May 11, 1981. 56(30000/28C)

Weyerhaeuser Company, Tacoma, WA. June 1, 1981. 48(30000/28C)

Witco Chemical, New York, NY. July 28, 1983. 80(30000/28C)

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Appendix A

Comparison of PD 2/3 Proposals with the Agency's Final Regulatory Measures

1. All Uses of Technical Pentachlorophenol and Pentachlorophenol Salts

Cancellation and denial of registrations of technical pentachlorophenol and salts of pentachlorophenol unless registrants modify the terms and conditions of registration to include the following information within 30 days after publication in the *Federal Register* of the Notice concluding the Wood Preservatives RPAR, or within 30 days of receipt of such Notice, whichever occurs later:

PD 2/3 Proposal	Final Regulatory Measures
No requirement proposed.	1. File an application to amend the Confidential Statements of Formula (CSF) to indicate that the hexachlorodibenzo-p-dioxin (HxCDD) contamination does not exceed 15 ppm and that 2,3,7,8-TCDD is below the limits of detection using a gas chromatography-mass spectrophotometry method of analysis acceptable to the Agency (e.g., Buser and Bosshardt, 1976). 2. File an application to amend the Confidential Statements of Formula for technical pentachlorophenol and pentachlorophenol salts to indicate that, effective 18 months after publication of the Notice or receipt by the registrant, whichever occurs later, the HxCDD contamination does not 1.0 ppm. (The method used to lower the HxCDD to 15.0 ppm or 1.0 ppm or lower must not increase the hexachlorobenzene or chlorinated dibenzofurans above the levels in products marketed at the time of publication of the FR Notice.)

2. All Uses of Pentachlorophenol
and Pentachlorophenol Salts

Cancellation and denial of registrations of all products containing pentachlorophenol and salts of pentachlorophenol unless registrants modify the terms and conditions of registration to include the following information within 30 days after publication in the **Federal** **Register** of the Notice concluding the Wood Preservatives RPAR, or within 30 days of receipt of such Notice, whichever occurs later:

PD 2/3 Proposal	Final Regulatory Measure
	Label Statement:
No requirement proposed.	1. The U.S. EPA has determined that pentachlorophenol can produce defects in the offspring of laboratory animals. Exposure to pentachlorophenol during pregnancy should be avoided.

3. Pressure-treatment Uses

Cancellation and denial of registrations of creosote, pentachlorophenol and inorganic arsenical products used for commercial pressure-treatment of wood unless the registrants modify the labeling of those creosote, pentachlorophenol and inorganic arsenical products to include the following information:

PD 2/3 Proposal	Final Agency Position
Not proposed	This pesticide product may not be used for treatment of wood or wood products for sale or distribution unless the wood treater is participating in or affiliated with a program adequate to inform users of the treated wood of the proper precautions to be taken in handling and using such treated wood. At a minimum wood treaters must: (1) distribute adequate consumer information sheets (CIS) with each shipment of pressure-treated wood so that at least one CIS will be securely attached to each bundle or batch of treated wood as it leaves the treating plant; (2) attach at least one CIS to each invoice for sale of pressure-treated wood; (3) make available to retailers, wholesalers and distributors an adequate supply of CIS's and signs or placards to inform consumers of the existence of the CIS's; and (4) encourage retailers to display signs or placards informing consumers of the availability of the CIS's and to make the CIS's readily available to the consumer. The information which the United States Environmental Protection Agency requires to be included in the CIS is found in the attached labeling.

3. Pressure-Treatment Uses (Cont'd)

PD 2/3 Proposal		Final Agency Position
		Model Consumer Information Sheets (CIS) to be distributed with each shipment of pressure-treated wood (Actual CIS will be separate for each chemical.)
(1) All individuals who handle pesticide-treated wood should wear gloves impervious to the wood preservatives (e.g., rubber).	(1) & (2)	Avoid frequent or prolonged skin contact with pentachlorophenol or creosote-treated wood; when handling the treated wood, wear tightly woven coveralls and use gloves impervious to the chemicals (for example, gloves that are vinyl-coated. When power sawing and machining, wear goggles to protect eyes from flying particles. Wash thoroughly after skin contact, and before eating, drinking, or use of tobacco products. If oily preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household clothing.
(2) Individuals who saw pesticide-treated wood should wear disposal coveralls (e.g., nitrile or polyethylene) or similar protective clothing (for homeowners tightly-woven cotton coveralls are acceptable).		
(3) Individuals who saw pesticide-treated wood and fabricate structures with treated wood should wear a dust mask capable of trapping 80% of particulates greater than 5 microns in size.		(3) Avoid frequent or prolonged inhalation of sawdust from treated wood. When sawing and machining treated wood, wear a dust mask. Whenever possible, these operations should be performed outdoors to avoid indoor accumulations' of airborne sawdust from treated wood.
(4) Treated wood should not be used indoors except for those support structures (e.g., foundation timbers, pole supports and the bottom six inches of stall skirt-boards) which are in contact with the soil in barns, stables, and similar sites (all three wood preservatives); all-weather wood foundations, sills and plates, structural framing (inorganic arsenicals only); millwork (pentachlorophenol only) which have outdoor	(4) & (5)	USE SITE PRECAUTIONS -- Wood treated with pentachlorophenol or creosote should not be used where it will be in frequent or prolonged contact with bare skin (for example, chairs and other outdoor furniture), unless an effective sealer * has been applied.

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* Coal tar pitch and coal tar pitch emulsions are effective sealers for creosote-treated wood block flooring. Urethane, shellac, latex Urethane, expoxy and shellac are acceptable sealers for all creosote-treated wood. epoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

3. Pressure-Treatment Uses (Cont'd)

PD 2/3 Proposal	Final Agency Position
surfaces (e.g., doorframes, windows and patio frames); and wood treated for sapstain control with 0.5% sodium pentachlorophenate.	-- Pentachlorophenol-treated wood should not be used in residential, industrial, or commercial interiors, except for laminated beams or building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.* Creosote-treated wood should not be used in residential interiors. Creosote-treated wood in interiors of industrial buildings should only be used for wood-block flooring and industrial building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.*
(5) Treated wood should not be used in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food creates, irrigation flumes, vegetables stakes, feedlot bins and watering troughs).	-- Exposed wood pressure-treated with waterborne arsenical preservatives may be used inside residences as long as all dust is vacuumed from the wood surface.
	-- Wood treated with pentachlorophenol or creosote should not be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bits) or lick the wood.
	-- In interiors of farm buildings where domestic animals or livestock are unlikely to crib (bite) or lick the wood, pentachlorophenol or creosote-treated wood may be used for building components which are in ground contact and are subject to decay or insect infestation and where two coats of an appropriate sealer are applied.*

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* Coal tar pitch and coal tar pitch emulsions are effective sealers for creosote-treated wood block flooring. Urethane, expoxy and shellac are acceptable sealers for all creosote-treated wood. Urethane, shellac, latex epoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

3. Pressure-Treatment Uses (Cont'd)

PD 2/3 Proposal	Final Agency Position
	-- Do not use pentachlorophenol or creosote-treated wood for farrowing or brooding facilities. -- Only treated wood that is visibly clean of surface residue should be used for patios, decks and walkways. -- Do not use treated wood under circumstances where the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food. -- Do not use treated wood for cutting boards or countertops. -- Do not use treated wood for construction of those portions of beehives which may come into contact with the honey. -- Pesticide-treated wood should not be used where it may come in to direct or indirect contact with public drinking water, except for uses involving incidental contact, such as docks and bridges. -- Do not use pentachlorophenol or creosote treated wood where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact, such as docks and bridges.
(6) Treated wood should not be burned, but should be disposed of by methods, such as on-site burial, which are in accordance with local and state laws, and/or the Resource Conservation and Recovery Act.	(6) Dispose of treated wood by ordinary trash collection or burial. Treated wood should not be burned in open fires or in stoves or fireplaces because toxic chemicals may be produced in the smoke and ashes. Large quantities of treated wood from commercial or industrial use (e.g., construction sites) may be burned in commercial or industrial incinerators in accordance with state and Federal regulations.

4. Pressure-Treatment Uses

Cancellation and denial of registrations of creosote, pentachlorophenol and inorganic arsenical products for wood preservatives use on railroad ties, lumber, timber and plywood, pilings, posts, crossarms, and poles unless the registrants modify the labeling of creosote, pentachlorophenol, and inorganic arsenicals products to include the following information:

PD 2/3 Proposal	Final Regulatory Measures
a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.	a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.
b. Protective Clothing and Equipment. (1) All applicators must wear gloves (e.g., rubber) in all situations where dermal contact with creosote, pentachlorophenol or inorganic arsenical is possible (e.g., handling treated wood and opening cylinder doors).	b. Protective Clothing and Equipment. (1) Applicators must wear gloves* impervious to the wood treatment formulation in all situations where dermal contact is expected (e.g., handling freshly treated wood and manually opening cylinder doors).
(2) Creosote and Pentachlorophenol. All applicators who open treatment cylinder doors must wear gloves and a properly maintained half-mask canister or cartidge respirator designed for pesticide use.	(2) Creosote: Applicators who manually open cylinder doors must wear gloves* and a respirator (properly fitting, well-maintained, half-mask canister or cartridge respirator which is MSHA/NIOSH-approved for polynuclear aromatics and organic vapors). Pentachlorophenol: Applicators who manually open cylinder doors must wear gloves* and a respirator (properly fitting, well-maintained, half-mask canister or cartridge respirator which is MSHA/NIOSH-approved for organic vapors and acid gases).

4. Pressure Uses, Cont'd.

PD 2/3 Proposal	Final Regulatory Measures
c. Applicators who enter pressure treatment cylinders and other related equipment must wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots, and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.	c. (1) Creosote & Pentachlorophenol. Applicators who enter pressure treatment cylinders and other related equipment that is contaminated with the wood treatment formulation (e.g., cylinders that are in operation or are not free of the treatment formulation) must wear protective clothing (including overalls, jacket, gloves and boots)* impervious to the wood treatment formulation and a respirator as described in b(2) above.
	c. (2) Inorganic Arsenicals. Applicators who enter pressure treatment cylinders and other related equipment that are contaminated with the wood treatment solution (e.g., cylinders that are in operation or are not free of the treatment solution) must wear protective clothing (including overalls, jackets, glove and boots)* impervious to the wood treatment formulation. In addition, employees who enter pressure-treatment cylinders must wear properly fitting, well-maintained high efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10 ug/m^3), averaged over an 8-hour work period. Air monitoring programs, procedures, and record retention and submission must be conducted in accordance with the instructions on the attached labeling material.

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*Examples of acceptable materials for protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of creosote are polyvinyl acetate (PVA), polyvinylchloride (PVC), neoprene, and NBR (Buna-N); for pentachlorophenol, acceptable materials are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile. In addition, plasticated disposable coveralls impervious to dust are acceptable for dust protection (pentachlorophenol). Examples of protective clothing (e.g., gloves, overalls, jackets, and boots) required during application and handling of inorganic arsenicals are vinyl, polyvinyl chloride (PVC), neoprene, NBR (Buna-N), rubber, and polyethylene.

4. Pressure Use Cont'd

PD 2/3 Proposal	Final Regulatory Measures
d. Applicators who work outdoors in arsenical wood treatment plants must wear a dust mask capable of trapping 80% of particulates greater than 5 microns in size.	d. Employees in the work area of an arsenical wood treatment plant must wear properly fitting, well maintained high efficiency filter respirators MSHA/NIOSH-approved for inorganic arsenic if the level of inorganic arsenic in the plant is unknown or exceeds 10 micrograms per cubic meter of air (10 ug/m^3) averaged over an 8-hour work period. Air monitoring programs, procedures and record retention and submission must be conducted in accordance with the instructions on the attached labeling material.
e. A closed emptying and a closed mixing system must be used for all powder formultions of the inorganic arsenicals.	e. A closed emptying and mixing system must be used for all powder formulations of the inorganic arsenicals. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding environment.
f. A closed emptying and a closed mixing system must be used for all prilled (granular) formulations of pentachlorophenol.	f. Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls) must be worn when emptying and mixing prilled or flaked formulations of pentachlorophenol. After September 1, 1987, a closed system must be used when emptying and mixing prilled or flaked formulations of pentachlorophenol. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment. Examples of acceptable respirators and protective clothing materials for pentachlophenol applicators are found in b(2) and c(1) above.
g. The inorganic arsenical treatment solutions must be filtered prior to use in the treatment cylinders and an additional vacuum step must be used prior to the removal of the treated wood from the treatment cylinders. In addition to these requirements, recommended control technologies to reduce the surface levels of arsenic on the treated wood include the use of wood that is free of heavy resins ("clean" wood), the post-treatment rinsing of the treated wood, and the installation of protective sheds or covers over the drying treated wood.	g. Processes used to apply inorganic arsenical formulations shall leave no visible surface deposits on the wood, as defined by AWPA Standard C-1 and AWPB Standards LP2 and LP22. (Visible surface deposits means a surface residue or crystallization on the treated wood. Small isolated or infrequent spots of chemical on otherwise clean wood shall be allowed.)

PD 2/3 Proposal	Final Regulatory Measures
h. All applicators must leave all protective clothing, work shoes or boots, and equipment at the plant at the end of the day. Worn-out protective clothing must be disposed of in accordance with the instructions for pesticide container disposal.	h. Pentachlorophenol and Creosote: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance. Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a general landfill, in the trash or in any other manner approved for pesticide disposal. Arsenic: Protective clothing must be changed when it shows signs of contamination. Applicators must leave protective clothing and equipment at the plant. Worn-out protective clothing and workshoes or boots must be left at the plant and disposed of in a manner approved for pesticide disposal and in accordance with State and Federal regulations. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
i. Eating, drinking and smoking are prohibited during the application of creosote, pentachlorophenol, and inorganic arsenical wood preservative pesticides by pressure treatment.	i. Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the wood treatment formulation (e.g., manually opening closing cylinder doors, moving trams out of cylinders, mixing chemicals and handling freshly treated wood). Wash thoroughly after skin contact, and before eating, drinking or use of tobacco products, or using restrooms.
j. (1) The application of creosote, pentachlorophenol, or inorganic arsenicals to wood which is intended for interior use is prohibited, except for those support structures (e.g., foundation timbers, pole supports and the bottom six inches of stall skirtboards) which are in contact with the soil in barns, stables and similar sites; inorganic arsenical-treated all-weather wood foundations, sills and plates, and structural framing. (2) Do not apply inorganic arsenicals, pentachlorophenol, or creosote to wood which will be used in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins and watering troughs).	j. (1) and (2) Not practical to enforce under FIFRA, because it would not be reasonable to expect the wood treater to know how the wood being treated and sold would be used. Instead, consumers will be informed about the proper use of treated wood by the Consumer Information Sheet distributed under the Consumer Awareness Program. (See Item 3 of Appendix.)

5. Groundline Treatment of Poles

Cancellation and denial of registration of creosote and pentachlorophenol products for wood preservatives use for groundline treatment of poles unless the registrants modify the labeling of creosote and pentachlorophenol products for the poles-groundline use to include the following information:

PD 2/3 Proposal	Final Regulatory Measures
a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.	a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.
b. Protective Clothing and Equipment. (1) All applicators must wear gloves impervious to the pentachlorophenol and creosote poles-groundline formulations (e.g., rubber) in all situations where dermal contact with pentachlorophenol and/or creosote is possible.	b. Protective Clothing and Equipment (1) Applicators must wear gloves impervious to the wood treatment formulation (e.g., polyvinyl acetate, polyvinyl chloride or neoprene) in all situations where dermal contact is expected (e.g., during the actual application process and when handling freshly treated wood).
(2) All applicators must wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing during the application process.	(2) Applicators must wear disposable coveralls (e.g., creosote: nitrile or neoprene; pentachlorophenol: nitrile or polyethelene) or other suitable impermeable protective clothing during the application and mixing processes in all situations where dermal contact is expected.
c. All applicators must dispose of worn-out protective clothing in accordance with the instructions for pesticide container disposal	c. Protective clothing must be changed when it shows signs of contamination. Launder non-disposable protective clothing separately from other household clothing. Dispose of worn-out shoes or boots in any general landfill, in the trash or in a other manner for pesticide disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidnace.
d. Eating, drinking and smoking are prohibited during the application of creosote and pentachlorophenol products for the poles-groundline use.	d. Applicators must not eat, drink, or use tobacco products during those parts of the application process which may directly expose them to the wood treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or before using restrooms.

6. Home and Farm

Cancellation and denial of registration of creosote and pentachlorophenol for non-pressure wood preservative home and farm use (including non-pressure use on railroad ties) unless the registrants modify the labeling of creosote and pentachlorophenol products for home and farm use to include the following information:

Home and Farm Use (Restricted)

PD 2/3 Proposal	Final Regulatory Measures
a. (1) For all creosote products and those pentachlorophenol products containing a pentachlorophenal concentration greater than 5%: Restricted Use Pesticide: For retail sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.	a. (1) and (2) For creosote and pentachlorophenol products registered for home and farm use (including use on railroad ties). Restricted Use Pesticide: For retail sale to and use only by certified applicators or persons under their direct supervision and only for the uses covered by the certified applicator's certification.
(2) Cancellation and denial of registration of the spray method of pentachlorophenol products which are available in concentration of 5% or less.	
b. Protective Clothing and Equipment	b. Protective Clothing and Equipment
(1) All applicators must wear gloves impervious to the creosote and pentachlorophenol treatment solutions (e.g., rubber) in all situations when dermal contact with these pesticides is possible (e.g., handling treated wood).	(1) For Restricted Use Products: Applicators must wear gloves impervious to the wood treatment formulation [e.g., pentachlorophenol: polyvinyl acetate (PVA), polyvinyl chloride (PVC), neonprene NBR (Buna-N), and nitrile; creosote: polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, and NBR (Buna-N)] in all situations where dermal contact is expected (for example, during the actual application process and when handling freshly treated wood).

PD 2/3 Proposal	Final Regulatory Measures
(2) All certified applicators who apply creosote and pentachlorophenol by the spray method must wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots, and a properly maintained half-mask canister or cartridge respirator designed for pesticide use, and all certified applicators who apply creosote and pentachlorophenol by other application processes (e.g., brush-on) must wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing.	(2) Restricted Uses: Spray applicators must wear protective clothing* (including overalls, jacket, gloves and boots) impervious to the wood treatment formulation and a respirator**, head covering, and goggles when spraying. Applicators who apply creosote and pentachlorophenol by other application processes (e.g., brush-on) must wear disposable coveralls or other suitable impermeable protective clothing. Launder non-disposable protective clothing separately from other clothing.
All non-certified applicators must wear tightly-woven, long sleeved cotton coveralls or similar protective clothing during the application process.	

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* Examples of protective clothing for restricted uses of creosote and pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile (pentachlorophenol only), Nitrile is also acceptable for disposable coveralls for creosote applicators.

** Respirators acceptable for use by applicators must be properly fitting, well-maintained half-mask canister or cartridge respirators which are MSHA/NIOSH-approved for polynuclear aromatics and organic vapors (creosote applicators) or for organic vapors and acid gases (pentachlorophenol applicators).

6. Home and Farm Use (Cont'd)

PD 2/3 Proposal	Final Regulatory Measures
c. All applicators applying creosote or pentachlorophenol solutions must dispose of worn-out protective clothing in accordance with the instruction for pesticide disposal.	c. Restricted Uses: Protective clothing must be changed when it shows signs of contamination. Dispose of worn-out protective clothing and workshoes or boots in any general landfill, in the trash, or in any other manner approved for pesticide disposal. For farm use or railroad tie repair: Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, of the Hazardous Waste representative at the nearest EPA Regional Office for guidance. For products for household/domestic use: Securely wrap original pesticide container in several layers of newspaper and discard in the trash. Do not reuse empty container.
d. Eating, smoking, and drinking are prohibited during the application of creosote or pentachlorophenol products.	d. Restricted Uses: Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.
e. The application of cresote and pentachlorophenol products indoors is prohibited. The application of creosote and pentachlorophenol products to wood intended for interior use is prohibited, except for those support structures (e.g., foundations timbers, pole supports, and the bottom six inches of stall skirtboards) which are in contact with the soil in barns, stables and similar sites, and millwork (pentachlorophenol only) which has outdoor surfaces (e.g., door frames, windows, and patio frames).	e. Restricted Uses: Pentachlorophenol and creosote: Avoid inhaling vapors. If inhalation of vapors cannot be avoided, applicators must wear a properly fitting, well-maintained half-mask or cartridge respirator which is MSHA/NIOSH-approved for organic vapors and acid gases (pentachlorophenol) or for polynuclear aromatics and organic vapors (creosote). Do not apply in interiors. Do not apply to wood intended for use in interiors, except for those support structures which are in contact with the soil in barns, stables and similar sites, and which are subject to decay or insect infestation; and millwork (pentachlorophenol only) which has outdoor surfaces (e.g., door-frames, windows, and patio frames). Interior surfaces of the treated wood should be sealed with two coats of an appropriate sealer. Urethane, epoxy, and shellac are acceptable sealers for all creosote-treated wood. Urethane, shellac, latex epoxy enamel and varnish are acceptable sealers for pentachlorophenol-treated wood.

PD 2/3 Proposal	Final Regulatory Measures
f. Do not use creosote or pentachlorophenol in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins, and watering troughs.)	f. Restricted Uses: Do not apply where there may be direct contact with domestic animals or livestock, and where there may be contamination of food, or drinking and irrigation water. Do not apply to wood intended for farrowing or brooding facilities. Do not apply to wood intended to be used in the interiors of farm buildings where there may be direct contact with domestic animals or livestock which may crib (bite) or lick the wood. Pentachlorophenol or creosote may be applied to wood intended to be used in interiors of farm buildings where domestic animals or livestock are unlikely to crib or lick the wood, and if two coats of an appropriat sealer will be applied. Do not apply to wood intended to be used in a manner in which the preservative may become a component of food or animal feed. Examples of such sites would be structures or containers for storing silage or food. Do not use this product to treat wood intended to be used for cutting boards or counter tops. Do not use this product to treat wood for construction of those portions of beehives which may come into contact with the honey. Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with public drinking water, except for those uses involving incidental contact such as docks and bridges.

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Do not use this product to treat wood intended to be used where it may come into direct or indirect contact with drinking water for domestic animals or livestock, except for uses involving incidental contact such as docks and bridges.

g. Other Precautions

Wood to be treated with this product should be cut to size before treatment. If it is necessary to saw or machine wood after treatment, wear goggles to protect the eyes from flying particles and a dust mask to avoid inhaling sawdust from the treated wood. If oily preservatives or sawdust accumulate on clothes, launder before reuse. Wash work clothes separately from other household laundry.

Contact with treated surfaces should be avoided even after the preservative has dried. When handling treated wood wear tightly woven coveralls and gloves which are impervious (e.g., vinyl coated) to the pesticide.

Wash exposed skin thoroughly after contact with treated wood, and before eating, drinking or using tobacco products.

Wood which has been treated with this product should be disposed of by burial or ordinary trash collection. Do not burn treated wood in an outdoor fire or in stoves or fireplaces, because toxic chemicals may be produced in the smoke and ashes.

This product should not be used to treat wood which will be in frequent or prolonged contact with skin, unless the wood will be treated with an effective sealer.

7. Brush-on Treatments of Inorganic Arsenicals

Cancellation and denial of registration of brush-on treatments of the inorganic arsenicals unless the registrants modify the labeling of the inorganic arsenical products to include the following information.

PD 2/3 Proposal	Final Regulatory Measures
a. Restricted-Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.	a. Unclassified Use
b. Protective Clothing and Equipment (1) All applicators must wear gloves impervious to the inorganic arsenical solutions (e.g., rubber) in all situations where dermal contact with the pesticide solution is possible (e.g., handling treated wood).	b. Protective Clothing and Equipment (1) Applicators must wear gloves (e.g., rubber, vinyl or neoprene) impervious to the wood treatment solution in all situations where dermal contact is expected (e.g., during the application process and handling freshly treated wood).
(2) All applicators must wear disposable coveralls (e.g., nitrile or polyethylene) or similar protective clothing during the application process.	(2) Applicators must wear disposable coveralls (e.g., vinyl or polyethelene) or other suitable impermeable protective clothing during the application process where dermal contact is expected.
c. Eating, drinking and smoking during the application of the inorganic arsenical products is prohibited.	c. Applicators must not eat, drink or use tobacco products during those parts of the application process which may directly expose them to the treatment solution. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products, or using restrooms.
d. All applicators applying brush-on inorganic arsenicals solution must dispose of worn-out protective clothing in accordance with the instructions for pesticide container disposal.	d. Protective clothing must be changed when it shows signs of contamination. Launder non-disposable protective clothing separately from other household clothing. Dispose of worn-out protective clothing in a manner approved for pesticide disposal and in accordance with State and Federal regulations. Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency; or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

7. Brush-on Treatments of Inorganic Arsenicals (Cont'd)

PD 2/3 Proposal	Final Regulatory Measures
e. Do not apply brush-on inorganic arsenical solution to wood intended for indoor use, except for those support structures (e.g., foundation timbers, pole supports and the bottom six inches of stall skirtboards) which are in contact with the soil in barns, stables and similar sites, all-weather wood foundations, sills and plates and structural framing.	e. & f. For application to the cut ends of pressure-treated wood only. Do not dilute or mix with other products. For commercial construction use only. Not for household use.
f. Do not use the inorganic arsenicals in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking or irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins and watering troughs).	

8. Non-Pressure Uses of Pentachlorophenol Salts for Sapstain Control

Cancellation and denial of registration of sodium pentachlorophenate products for sapstain control __unless__ the registrants modify the labeling of sodium pentachlorophenate products to include the following information:

PD 2/3 Proposal	Final Regulatory Measures
a. __Restricted Use Pesticide__: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.	a. __Restricted Use Pesticide__: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by certified applicator's certification.
b. __Protective Clothing and Equipment__: (1) All applicators using sodium pentahchlorophenate for sapstain control must wear gloves impervious to sodium pentachlorophenate (e.g., rubber) in all situations where dermal contact with sodium pentachlorophenate is possible (e.g., handling treated wood).	b. __Protective Clothing and Equipment__ (1) All applicators must wear gloves impervious to the wood treatment formulation in all situations where dermal contact is expected (for example, during the application process and when handling freshly treated wood) *
(2) All applicators who apply sodium pentachlorophenate formulations by the spray method must wear gloves and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.	(2) For the spray method of application: spray apparatus must (1) be operated so as to minimize overspray (i.e., no visible mist) and (2) be free of leaks in the system. Should there be a visible mist, spray applicators in the vicinity of the apparatus (the zone in which the mist is visible) must wear a respirator* and protective clothing (including overalls, jacket, boots, head covering impervious to the wood treatment formulation, and goggles).
(3) All individuals who enter or clean vats and other related equipment must wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.	(3) Individuals who enter, clean, or repair vats, tanks or other related equipment that are contaminated with the treatment solution must wear a respirator.* In addition, when dermal contact is expected, these individuals must wear overalls, jackets, boot, head covering impervious to the wood treatment formulation and goggles.*

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* Respirators must be properly fitting, well-maintained, half-mask canister or cartridge respirators, which are MSHA/NIOSH-approved for organic vapors. Examples of acceptable materials for protective clothing (e.g., overall, jackets, head covering, boots, disposable coveralls, and gloves) required are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile.

8. Non-Pressure Uses of Pentachlorophenol Salts for Sapstain Control (Cont'd)

PD 2/3 Proposal	Final Regulatory Measures
c. A closed emptying and a closed mixing system must be used for all prilled (granular) and powder formulations of sodium pentachlorophenate;	c. Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator*, gloves* and tightly woven, long-sleeved cotton or disposable coveralls*) must be worn when emptying and mixing powder formulations of pentachlorophenate. After September 1, 1987, a closed system must be used when emptying and mixing powder formulations of pentachlorophenate. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.
d. All sapstain control applicators must leave all protective clothing, work shoes or boots and at the plant. Worn-out protective clothing must be disposed of following the instructions for pesticide container disposal.	d. Protective clothing must changed when it shows signs of contamination. Applicators must equipment leave all protective clothing, work shoes or boots and equipment at the plant. Worn-out protective clothing and work shoes or boots must be left at the plant and disposed of in any general landfill in the trash, or in any other manner approved for pesticide disposal. Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
e. Eating, drinking and smoking is prohibited during the application of sodium pentachlorophenate for sapstain control.	e. Applicators must not eat, drink, or use tobacco products during those parts of the application process which any expose them to the treatment formulation. Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products or using restrooms.
f. Do not use sodium pentachlorophenate for sapstain control in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feed lot bins and watering troughs).	f. No regulation (minimal exposure).

9. Millwork and Plywood & Particleboard and Logs for Log Homes

Cancellation and denial of registration of the wood preservative use of pentachlorophenol for millwork, plywood, and particleboard and logs for construction of log homes unless the registrants modify the labeling of pentachlorophenol products for the millwork, plywood, and particle board uses to include the following information:

PD 2/3 Proposal	Final Regulatory Measures
a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by the certified applicator's certification.	a. Restricted Use Pesticide: For sale to and use only by certified applicators or by persons under their direct supervision and only for those uses covered by certified applicator's certification.
b. Protective Clothing and Equipment: (1) All applicators applying pentachlorophenol must wear gloves impervious to the wood treatment solution (e.g., rubber) in all situations where dermal contact with the treatment solutions is possible (e.g., handling treated wood).	b. Protective Clothing and Equipment (1) Applicators must wear gloves impervious to the wood treatment formulation in all suitations where dermal contact is expected (for example, during the application process and when handling freshly treated wood).*
(2) All applicators who apply pentachlorophenol to millwork and plywood by the spray method must wear gloves and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.	(2) For the spray method of application, spray apparatus must (1) be operated so as to minimize overspray (i.e., no visible mist) and (2) be free of leaks in the system. Should there be a visible mist, spray applicators in the vicinity of the apparatus (the zone in which the mist is visible) must wear a respirator* and protective clothing (including overalls, jackets, boots, head covering impervious to the wood treatment formulation, and goggles).
(3) All individuals who enter or clean vats and other related equipment must wear a neoprene-coated cotton or rubberized overall, jacket, gloves and boots and a properly maintained half-mask canister or cartridge respirator designed for pesticide use.	(3) Individuals who enter, clean or repair vats, tanks, or other related equipment that are contaminated with the treatment solution must wear a respirator.* In additition, when dermal contact is expected, these individuals must wear overalls jacket, boots, head covering impervious to the wood treatment formulation, and suitable eye goggles.

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* Respirators must be properly fitting, well-maintained half-mask canister or cartridge respirators, which are MSHA/NIOSH-approved for organic vapors and acid gases. Examples of acceptable materials for protective clothing (e.g., overalls, jackets, head covering, boots, disposable coveralls and gloves) required during the application and handling of pentachlorophenol are polyvinyl acetate (PVA), polyvinylchloride (PVC), neoprene, NBR (Buna-N), and nitrile. In addition, plastic-coated disposable coveralls impervious to dust are acceptable for dust protection.

9. Millwork and Plywood & Particleboard and Logs for Log Homes (Cont'd)

PD 2/3 Proposal	Final Regulatory Measures
c. A closed emptying and a closed mixing system must be used for all prilled (granular) formulations of pentachlorophenol.	c. Until August 31, 1987, a closed emptying and mixing system must be used or protective clothing (including respirator, gloves and tightly woven, long-sleeved cotton or disposable coveralls)* must be worn when emptying and mixing prilled or flaked formulations of pentachlorophenol. After September 1, 1987, a closed system must be used when emptying and mixing prilled or flaked formulations of of pentachlorophenol. A closed system is defined as any containment which prevents the release of subject chemicals into the surrounding external environment.
d. All applicators who apply pentachlorophenol to millwork, plywood and particleboard must leave all protective clothing, work shoes or boots, and equipment at the plant at the end of day. Worn-out protective clothing must be disposed of following the instructions for pesticide container disposal.	d. Protective clothing must be changed when it shows signs of contamination. Applicators must leave all protective clothing, workshoes or boots, and equipment at the plant. Worn-out protective clothing and work-shoes or boots must be left at the plant and disposed of in any general landfill, in the trash, or in any other manner approved for pesticide disposal.
	Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.
e. Eating, drinking and smoking is prohibited during the application of pentachloropenol to millwork, plywood, and particleboard.	e. Applicators must not eat, drink, or use tobacco products during those parts of the application process which may expose them to the treatment formulation.
	Wash thoroughly after skin contact, and before eating, drinking, use of tobacco products or using restrooms.

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* Respirators must be properly fitting, well-maintained half-mask canister or cartridge respirators, which are MSHA/NIOSH-approved for organic vapors and acid gases. Examples of acceptable materials for protective clothing (e.g., overalls, jackets, head covering, boots, disposable coveralls and gloves) required during the application and handling of pentachlorophenol are polyvinyl acetate (PVA), polyvinyl chloride (PVC), neoprene, NBR (Buna-N), and nitrile. In addition, plastic-coated disposable coveralls impervious to dust are acceptable for dust protection.

9. Millwork and Plywood & Particleboard (Cont'd)

PD 2/3 Proposal	Final Regulatory Measures
f. Interior Use Millwork and Plywood: The application of pentachlorophenol products to wood intended for interior use is prohibited, except for wood which has outdoor surfaces (e.g., doorframes, windows and patio frames). Particleboard: The application of pentachlorophenol to particleboard intended for any interior use (e.g., kitchen cabinets) is prohibited.	f. & g. No regulation for millwork, plywood and particleboard (minimal exposure). - Do not apply to logs which are intended for use in the construction of log homes.
g. Do not use pentachlorophenol in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins and watering troughs).	

10. Data Requirements [FIFRA 3(c)(2)(B)]

In an action separate from this PD 4, registrants will be required to submit certain data to maintain existing registrations in effect pursuant to FIFRA 3(c)(2)(B).

PD 2/3 Proposal	Final Regulatory Measures
No proposal.	a. Registrants of products containing technical pentachlorophenol or pentachlorophenol salts will be required to submit the following: 1. A description of the starting materials, manufacturing process and reaction conditions including any steps to reduce HxCDD. 2. Information on product identity relative to identification of ingredients, statement of composition and a discussion of the formation of impurities. 3. Data on the analysis and certification of product ingredients relative to preliminary analysis, certification of limits, and analytical methods for the envorcement of limits. An analytical method employing combined gas chromatography and mass spectrophotometry is acceptable (e.g., Buser and bosshardt, 1976). 4. HxCDD analyses every three months, the first analysis to be submitted within the stated 90-day period. 5. A description of any changes in the manufacturing process used to lower HxCDD to 15 ppm and/or 1 ppm or lower must also be submitted within the stated time period of 90 days. The methods used to lower HxCDD must not increase the chlorinated dibenzofurans and HCB contaminants above the levels in products marketed at the time of publication of the FR Notice. 6. Information on the technical feasibility and costs of reducing HxCDD contamination further.

10. Data Requirements [FIFRA 3(c)(2)(B)] (Cont'd)

In an action separate from this PD 4, registrants will be required to submit certain data to maintain existing registrations in effect pursuant to FIFRA 3(c)(2)(B).

PD 2/3 Proposal	Final Regulatory Action
	b. Registrants of creosote will be required to submit the following:
	1. Retrospective epidemiology study on workers at creosote treatment plants.
	2. Air monitoring and dermal exposure data from cresote-treatment plants.
	c. Registrants of creosote and arsenic will be required to submit the following:
	1. Data on permeability of glove and protective clothing materials indicating degree of protection for creosote and inorganic arsenical formulations.
	d. Registrants of bis(tri-n-butyltin) oxide, acid copper chromate, chromated zinc chloride, sodium tetrachlorophenate, copper-8-quinolinolate, copper naphthenate, zinc naphthenate and 3-iodo-2-propynyl butylcarbamate, and barium metaborate will be required to submit the following:
	1. Chronic feeding studies 2. Oncogenicity studies 3. Reproduction studies 4. Teratology studies.
	e. Registrants of pentachlorophenol will be required to submit inhalation and dermal exposure data for spray applications of pentachlorophenol products for home and farm use.

APPENDIX B

Comparison of Risks for Pentachlorophenol and the Inorganic Arsenicals Calculated in the PD 2/3, with and without Proposed Protective Measures, with the recalculated Risks with and without Required Protective Measures (Final Regulatory Measures)

Appendix B

Pentachlorophenol (Penta)

Note: The estimates for the oncogenicity and fetoxicity/teratogenic risks for pentachlorophenol for the PD4 were summarized from Rispin (1984). PD 2/3 pentachlorophenol and sodium pentachlorophenate risks were based on a dermal absorption rate of 10%; the 1-hit oncogenic risk model was used. The PD4 risks for HxCDD were based on a dermal absorption rate of 50% (Rispin April 24, 1984). The multi-stage oncogenic risk model was used for the PD4 risk estimates (Rispin, April 18, 1984, and McGaughy, April 24, 1984). MOS (Margins of Safety) estimates for teratogenic/fetotoxic risks are rounded off to two significant figures and assume a 50% dermal absorption rate for liquid pentachlorophenol and 1% for dry formulations. For a detailed summary of exposure assumptions, see Appendix C.

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures) HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (PD 2/3) HxCDD(15 ppm) (onco)	Penta MOS	Initial Risk (PD/4) Without Protective Measures HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (Final PD4 Requirement) HxCDD(1 ppm) (onco)	Penta MOS
1. Pressure treatment plants								
a. Opening cylinder doors [1]	6.4×10^{-4}	150	Require gloves and respirator 6.4×10^{-5}	1,500	4.3×10^{-4}	150	Require gloves and a respirator (total dermal risk reduced 80%) 3.1×10^{-6}	1500
b. Entering[2] cylinders	Not determined	Not determined	Wear protective clothing and respirator. (Reduce dermal exposure by 80% & inhalation exposure by 90%.)		Not determined	Not determined	Wear protective clothing and a respirator. (Reduce total dermal exposure by 80% and inhalation exposure by 90%.)	

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[1] Dermal exposure not determined.

[2] The PD 2/3 and PD4 information for applicators entering cylinders also applies to millwork and plywood applicators who enter, clean, or repair vats or other related equipment that is contaminated with the treatment solution.

Appendix B (Continued)

Pentachlorophenol (Penta)

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures) HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (PD 2/3) HxCDD(15 ppm) (onco)	Penta MOS	Initial Risk (PD4) Without Protective Measures HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (Final PD4 Requirement) HxCDD(1 ppm) (onco)	Penta MOS
c. bag emptying*	1.5×10^{-2} to 7×10^{-3}	227 to 470	Require closed emptying and mixing systems. Assume minimal exposure and risk.		4.3×10^{-3} to 3.5×10^{-2}	43 to 23	In three years, require closed emptying and mixing systems. (Assume minimal exposure and risk.) In the meantime, require protective clothing and a respirator. 4.3×10^{-4} to 4.3×10^{-5}	 400 to 160

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* The PD4 risks were calculated based on the assumption that an applicator empties/mixes the formulation a maximum of 2 hrs/day for 2 days/week. The PD 2/3 and PD4 information for bag emptying also applies to millwork and plywood applicators who empty and mix bags of prilled or flaked formulations of pentachlorophenol and to applicators emptying and mixing bags of powdered sodium pentachlorophenate for use in sapstain control.

Appendix B (continued)

Pentachlorophenol (Penta)

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures)		Risk with Protective Measures (PD 2/3)		Initial Risk (PD 4) Without Protective Measures		Risk with Protective Measures (Final PD 4 Requirement)	
	HxCDD(15 ppm) (onco)	Penta MOS	HxCDD(15 ppm) (onco)	Penta MOS	HxCDD(15 ppm) (onco)	Penta MOS	HxCDD(1 ppm) (onco)	Penta MOS
2. Non-pressure treatment uses								
a. Poles/ Groundline	Not determined	Not determined	Require gloves and protective clothing. (Reduce total dermal exposure by 80%.)		Not determined	Not determined	Require gloves and protective clothing. (Reduce total dermal exposure 80%.)	
b. Millwork/plywood [4]								
i.) Dip/flow (5.0%)	7.1×10^{-3}	5.9	Require gloves 7.1×10^{-5}	210[1]	6.6×10^{-2}	1.2	Require gloves 4.3×10^{-4}	12
ii.) Spray (2.5%)	[2]9.8×10^{-3}	[2] 10	Require gloves and respirator 2.4×10^{-4}[2]	400[2]	[3]3.3×10^{-2}	[3]2.4	Require gloves [3]1.9×10^{-4}	[3] 23
							In addition require respirator and protective clothing if visible mist present in the vicinity of the apparatus.	
					[2]3.4×10^{-2}	[2]2.3	[2]2.5×10^{-4}	[2] 23

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[1] Van Ormer (1982d) has corrected this PD 2/3 MOS number to 590.

[2] Assuming the applicator is in the vicinity of the enclosed spray apparatus and is exposed to both HxCDD and Pentachlorophenol (dermal and inhalation).

[3] Assuming the applicator is 30 to 40 feet away from the enclosed spray apparatus, is only exposed to pentachlorophenol vapors, not HxCDD, but is exposed dermally (hand contact) with the treatment solutions.

[4] The Agency considered cancelling registrations of pentachlorophenol for millwork and plywood use because of the potential oncogenic and teratogenic/fetotoxic risks. While the economic impacts of a cancellation are considered to be minor in terms of absolute dollars (Section II.C.2.d. of this PD 4), the impact would be significant for users who would not have an equally efficacious alternative chemical to apply. Section VI.H.1. of this PD 4 discusses in detail the bases for not cancelling pentachlorophenol registrations for this use.

Appendix B (continued)
Pentachlorophenol (Penta)

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures) HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (PD 2/3) HxCDD(15 ppm) (onco)	Penta MOS	Initial Risk (PD/4) Without Protective Measures HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (Final PD4 Requirement) HxCDD(1 ppm) (onco)	Penta MOS
c. Sapstain (Sodium pentachlorophenate)								
i.) Dip/flow[3] (5%)	7.1 x 10^{-4}	59	Require gloves 7.1 x 10^{-6}	6,000	6.6 x 10^{-2}	60	Require gloves 4.3 x 10^{-4}	600
ii.) Sapstain Spray (0.5% Solution)	[1] 1.9 x 10^{-3}	[1] 50	Require gloves and respirator [1] 4.8 x 10^{-5}	[1] 2,000	[2] 6.8 x 10^{-3}	[2] 440	Require gloves. [2] 4.3 x 10^{-5} In addition require respirator and protective clothing if visible mist present in the vicinity of the apparatus	[2] 1300
					[1] 6.8 x 10^{-3}	[1] 200	[1] 3.8 x 10^{-5}	[1] 2000

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[1] Assuming the applicator is in the vicinity of the apparatus and is exposed to both HxCDD and pentachlorophenol (dermal and inhalation).

[2] Assuming the applicator is 30 to 40 feet away from the enclosed spray apparatus, is only exposed to pentachlorphenol vapors (not HxCDD), but is exposed dermally (hand contact) to the treatment solutions. The Agency assumed that an applicator may spill 6.0 mls of a 5% sodium pentachlorophenate solution to cover the hands (Day, 1982).

[3] Assume a 5% solution of sodium pentachlorophenate, a 50% dermal absorption rate for HxCDD and a 1% dermal absorption rate for sodium pentachlorophenate in an aqueous solution (Rispin, 1984).

Appendix B (continued)

Pentachlorophenol (Penta)

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures) HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (PD 2/3) HxCDD(15 ppm) (onco)	Penta MOS	Initial Risk (PD/4) Without Protective Measures HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (Final PD4 Requirement) HxCDD(1 ppm) (onco)	Penta MOS
d. Home and Farm								
i.) Brush-on*								
-Indoor Application	1×10^{-4}	6	Prohibit indoor application. No risk.		6.2×10^{-4}	1.2	Prohibit indoor application. No risk.	
-Outdoor Application	1×10^{-4}	6	Require gloves 1.3×10^{-6}	560	6.2×10^{-4}	1.2	Require gloves. Use respirators during application if inhalation of vapors cannot be avoided. 6.2×10^{-6}	12 Reduce acute toxicity due to inhalation of vapors by 90%.
ii. Spray Application	Not determined	Not determined	Require respirator and protective clothing. (Reduce total dermal exposure by 80% and inhalation exposure by 90%.)		Not determined	Not determined	Require respirator and protective clothing. (Reduce total dermal exposure 80% and inhalation exposure 90%.)	

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* The PD4 oncogenicity risks for brush-on home and farm applications were calculated based on the assumption that an applicator applies the formulation once every three years for 2 weeks duration (Burnam, 1983). The Agency also assumed that an applicator may spill 6.0 mls of a 5% pentachlorophenol solution to cover the hands (Day, 1982). For a home and farm user who does odd jobs outdoors and who may use pentachlorophenol more frequently, the Agency calculated the potential risks as follows: if a worker applies a 5% pentachlorophenol solution 120 days per year for a 30 year working lifetime the oncogenic risk is 2.6×12^{-2}(15 ppm HxCDD) and 2.1×10^{-3} (1 ppm HxCDD) if no gloves are worn. The risk is 2.1×10^{-4} (1 ppm HxCDD) if impermeable gloves are worn. The MOS for fetotoxic effects is 12.

Appendix B (continued)

Pentachlorophenol (Penta)

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures) HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (PD 2/3) HxCDD(15 ppm) (onco)	Penta MOS	Initial Risk (PD/4) Without Protective Measures HxCDD(15 ppm) (onco)	Penta MOS	Risk with Protective Measures (Final PD4 Requirement) HxCDD(1 ppm) (onco)	Penta MOS
3. Interior Use of treated wood.								
a. Occupational End-Use. Poorly Ven-	Negligible	510	Prohibit interior use. No risk		Negligible	4300 to 1000	Prohibit interior use except for support structures where necessary. Require Sealers Negligible	7,500 to >10,000
					Acute toxicity		Reduce acute toxicity 80%.	
b. Occupational End-Use. Well ventilated.	Negligible	7,900	Prohibit interior use. No risk.		Negligible	7,900	Prohibit interior use except for support structures where necessary. Require sealers. Negligible	>10,000
					Acute toxicity		Reduce acute toxicity 80%	

Appendix B (continued)

Pentachlorophenol (Penta)

Exposure Situation	Initial Risk (PD 2/3) (Without Protective Measures)		Risk with Protective Measures (PD 2/3)		Initial Risk (PD/4) Without Protective Measures		Risk with Protective Measures (Final PD4 Requirement)	
	HxCDD(15 ppm) (onco)	Penta MOS	HxCDD(15 ppm) (onco)	Penta MOS	HxCDD(15 ppm) (onco)	Penta MOS	HxCDD(1 ppm) (onco)	Penta MOS
c. Residential end-use of commercial dip/pressure treated wood	Not determined		Prohibit interior Use		Negligible	940 to 4000	Prohibit interior use except for support structures where necessary. Require sealers. Negligible.	6,300 to >10,000
					Acute toxicity		Reduce acute toxicity by 80%. Prohibit use of nonpressure penta treated logs for log homes.	No risk
d. Residual end-use of aged treated	Not Determined		Prohibit interior use		Negligible	1,900 to 38,000	Prohibit interior use except for support structures where necessary. Require Sealers. Negligible.	>10,000
					Acute toxicity		Reduce acute toxicity by 80%.	

Appendix B (continued)

Inorganic Arsenic

NOTE:
The estimates for oncogenicity risks for inorganic arsenic were summarized from Rispin (April 18, 1984). Data were inadequate to allow calculation of a NOEL for teratogenic/fetotoxic effects; thus, MOS risks were not estimated (Sochard, 1983). The PD 2/3 inhalation and dermal oral risks were calculated using linear dose-response risk models based on epidimiological data (PD 2/3, p. 215). The PD4 inhalation risks were also calculated using a linear dose response model but were based on new epidimiological data (U.S. EPA, June 1983; McGaughy, April 24, 1984; and Rispin, April 18, 1984). The PD4 dermal/ oral risks were calculated using a linear dose response model different from that of the PD 2/3, but using the same epidimiological data (U.S. EPA, June 1983; McGaughy, April 24, 1984; and Rispin, April 18, 1984). For a detailed summary of exposure assumptions, see Appendix C.

Exposure Situation	Initial Risk (PD 2/3) Without Protective Measures Oncogenic	MOS	Risk with Protective Measures (PD2/3) Oncogenic	MOS	Initial Risks (PD/4) Without Protective Measures (Onco)	Risk with Protective Measures (Final PD4 Requirement Oncogenic
1. Pressure treatment Plant						
a. Exposure to ambient arsenic*	1.9×10^{-2}	500	Require dust masks 3.8×10^{-3}	2,500	4.1×10^{-3}*	Require respirators if the arsenic level is unknown or exceeds 10 ug/m^3. 4.1×10^{-5}*
b. Opening cylinder doors	Not determined		Require gloves (Reduce dermal exposure by 99%)		Not Determined	Require gloves (reduce dermal exposure by 90%)
c. Entering cylinder	Not determined		Require protective clothing and respirator (Reduce inhalation exposure by 90% and dermal exposure by 80%.)		Dermal risk not determined.	Require protective clothing to reduce total dermal exposure by 80%.
					4.1×10^{-3}*	If 10 ug/m^3 exceeded or unknown require respirators. 4.1×10^{-5}*

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* Inhalation risks based on an assumed exposure of 10 ug/m^3 inorganic arsenic levels in the air averaged over an 8-hour workday (Rispin, April 18, 1984).

Appendix B (continued)

Inorganic Arsenic

Exposure Situation	Initial Risk (PD 2/3) Without Protective Measures Oncogenic	Initial Risk (PD 2/3) Without Protective Measures MOS	Risk with Protective Measures (PD 2/3) Oncogenic	Risk with Protective Measures (PD 2/3) MOS	Initial Risk (PD/4) Without Protective Measures (onco)	Risk with Protective Measures (Final PD4 Requirement) Oncogenic
d. Handling freshly treated wood and mixing dilute formu-	(d + i) 2.6 x 10^{-2}	(d + i) 417	Require gloves (d + i) 1.9 x 10^{-2}	(d + i) 499	6.2 x 10^{-3} (d)	Require gloves (reduce dermal exposure 90%) 6.2 x 10^{-4} (d)
					4.1 x 10^{-3} (i)*	Require gloves and respirator if 10 ug/m^3 arsenic is exceeded or unknown. 4.1 x 10^{-5} (i)*
e. Bag emptying	3.4 x 10^{-2}	294	Require closed systems. (minimal risk)		7.3 x 10^{-3} (d) 4.1 x 10^{-3} (i)*	Require closed systems. (minimal risk)
2. Brush-on Applications	1.2 x 10^{-2}	1,667	Require gloves and coveralls 1.2 x 10^{-4}	170,000	2.8 x 10^{-3} (d)	Require gloves and coveralls 2.8 x 10^{-4} (d)
3. Interior Uses	9.0 x 10^{-6}	128,000	Prohibit interior uses except for all-weather wood foundations, plates, sills, structural framing, timbers, and pole supports.		4.7 x 10^{-5}(i)**	Allow interior uses of arsenic pressure - treated wood. 4.6 x 10^{-6} (i)***

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* Inhalation risks based on an assumed exposure of 10 ug/m^3 arsenic in ambient air averaged over an 8-hour work day (Rispin, April 18, 1984).

** Based on 0.031 ug/m^3 arsenic air levels (PD 2/3, p. 200).

*** Based on 0.004 ug/m^3 arsenic air levels (Koppers, Nov. 15, 1983) where wood surfaces were vacuumed to be free of dust.

Exposure Situation	Inorganic Arsenic Initial Risk (PD 2/3) Without Protective Measures Oncogenic	MOS	Risk with Protective Measures (PD 2/3) Oncogenic	MOS	Initial Risk (PD/4) Without Protective Measures (onco)	Risk with Protective Measures (Final PD4 Requirement) Oncogenic
4. Sawing/ fabricating treated wood.**			Require dust masks and coveralls			Require dust masks
	1.3 x 10^{-1} to 1.6 x 10^{-1}	128 to 106	2.7 x 10^{-3} to 3.0 x 10^{-3}	>3,000	3.1 x 10^{-4} CCA (g) 7.6 x 10^{-4} ACA (g) 8.6 x 10^{-4} CCA (i) 2.1 x 10^{-3} ACA (i)	6.2 x 10^{-5} CCA (g) 1.5 x 10^{-4} ACA (g) 1.7 x 10^{-4} CCA (i) 4.2 x 10^{-4} ACA (i)

** PD 2/3 risks (p. 701) based on dermal, inhalation, and gastrointestinal exposure. PD 4 risks based on inhalation and gastrointestinal exposure, assuming negligible exposure from dermal contact with arsenic treated wood (Zendzian, 1982).

d = dermal; i = inhalation; g = gastrointestinal exposure

APPENDIX C

Comparison of the Recalculated Exposures for Pentachlorophenol and Inorganic Arsenic With and Without Protective Measures (Final Regulatory Position)

Exposure Assumptions for Appendix C

Inorganic Arsenic

1. The dermal absorption for inorganic arsenic solutions (1.7% ACA solution for pressure treatments) and treated wood which subsequently becomes wet with water is 0.1%. Six mls are assumed to contact the hands.*

2. The dermal absorption for dry inorganic arsenic (powder or arsenic-laden dust) is 0.1%.** FCAP (Fluor chrome arsenic phenol) is assumed to contain 9.59% arsenic as metal.*

   The dermal exposure for 1 hour of bag emptying is estimated to range from 3.8 to 142 mg/hr,* based on Comer (1975), Jegier (1964), and Wolfe (1976).

3. The dermal absorption for inorganic arsenic from dry treated wood and arsenic-laden sawdust is negligible.***

4. The inhalation and gastrointestinal absorption rates and depositon rates for sawdust from nailing, sawing, or fabricating arsenic-treated wood are:*

   27% for CCA (chromated copper arsenate)
   65% for ACA (ammoniacal copper arsenate)
   10% of the sawdust particles are respirable
   90% of the sawdust particles will be ingested

5. For brush-on application, the arsenic concentration is assumed to be 3.3%.* Inhalation risk is assumed to be minimal (PD 1, 43 FR 48267) because it is applied as a viscous liquid and vapor pressure is low. The PD 2/3 (p. 211) stated that this exposure was "intermittent." When risks were calculated in this PD 4, it was assumed that 6.0 mls covers both hands during an accidental exposure and that this may occur 60 days per year (Smale, May 11, 1984).

6. The inhalation and gastrointestinal absorption rate for arsenic from arsenic-laden dust and for water soluble salts of inorganic arsenic is 100%,* because there are no data to indicate otherwise.

7. The time a resident spends at home is 15 hours a day.*

8. The estimated concentration of inorganic arsenic in the air at treatment plants is 10.0 ug/m^3,* based on measured levels reported in the PD 1 (43 FR 48267) and data submitted by AWPI (36C:30000/28C).

9. The estimated inhalation exposure in homes with all-weather-wood foundations is 0.004 ug/m^3 based on data submitted by Koppers (Nov. 15, 1983).

10. The estimated inorganic arsenic air concentration while nailing, sawing, or fabricating with arsenic-treated wood is 0.024 mg/m^3,* based on a study submitted by AWPI (#36C: 30000/28C) from the University of Minnesota.

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* Day, May 19, 1982; revised January 25, 1984; and Rispin, 1984.
** Day, December 9, 1983; and Rispin, 1984.
***Zendzian, April 16, 1982; and Rispin, 1984.

11. For pentachlorophenol surface spray treatments, the inhalation exposure in the vicinity of the spray booth is estimated, in the absence of other data, to be 5 times that of sapstain spray treatments as per PD 2/3 (p. 322), because the pentachlorophenol solution (2.5%) is 5 times as concentrated as the sodium pentachlorophenate solution (0.5%).*

12. With sealants, the indoor pentachlorophenol air concentration is reduced about 85%.*

13. Home and farm applicators use pentachlorophenol for a two-week duration once every three years.*** This time estimate was taken into account when the risks were calculated. Six mls of a 5% soution is assumed to cover both hands during an accidental spill.

14. As in the PD 2/3 (p. 316), the Agency assumes the pentachlorophenol inhalation exposure while opening cylinder doors is 1.0 mg/m^3 based on data from Arsenault (1976). It was assumed that workers engage in this light activity 1 hour per day. HxCDD inhalation exposure was estimated also,* since mist formation is likely to occur (PD 2/3, p. 299 and p. 338).

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* Day, May 19, 1982; amended January 25, 1984; and Rispin, April 18, 1984.

** Day, December 9, 1983; and Rispin, 1984.

***Burnam, Dec. 2, 1983; and Rispin, 1984.

Exposure Assumptions for Appendix C

Inorganic Arsenic

1. The dermal absorption for inorganic arsenic solutions (1.7% ACA solution for pressure treatments) and treated wood which subsequently becomes wet with water is 0.1%. Six mls are assumed to contact the hands.*

2. The dermal absorption for dry inorganic arsenic (powder or arsenic-laden dust) is 0.1%.** FCAP (Fluor chrome arsenic phenol) is assumed to contain 9.59% arsenic as metal.*

   The dermal exposure for 1 hour of bag emptying is estimated to range from 3.8 to 142 mg/hr,* based on Comer (1975), Jegier (1964), and Wolfe (1978).

3. The dermal absorption for inorganic arsenic from dry treated wood and arsenic-laden sawdust is negligible.***

4. The inhalation and gastrointestinal absorption rates and depositon rates for sawdust from nailing, sawing, or fabricating arsenic-treated wood are:*

   27% for CCA (chromated copper arsenate)
   65% for ACA (ammoniacal copper arsenate)
   10% of the sawdust particles are respirable
   90% of the sawdust particles will be ingested

5. For brush-on application, the arsenic concentration is assumed to be 3.3%.* Inhalation risk is assumed to be minimal (PD 1, 43 FR 46267) because it is applied as a viscous liquid and vapor pressure is low. The PD 2/3 (p. 211) stated that this exposure was "intermittent." When risks were calculated in this PD 4, it was assumed that 6.0 mls covers both hands during an accidental exposure and that this may occur 60 days per year (Smale, May 11, 1984).

6. The inhalation and gastrointestinal absorption rate for arsenic from arsenic-laden dust and for water soluble salts of inorganic arsenic is 100%,* because there are no data to indicate otherwise.

7. The time a resident spends at home is 15 hours a day.*

8. The estimated concentration of inorganic arsenic in the air at treatment plants is 10.0 ug/m^3,* based on measured levels reported in the PD 1 (43 FR 48267) and data submitted by AWPI (36C:30000/28C).

9. The estimated inhalation exposure in homes with all-weather-wood foundations is 0.004 ug/m^3 based on data submitted by Koppers (Nov. 15, 1983).

10. The estimated inorganic arsenic air concentration while nailing, sawing, or fabricating with arsenic-treated wood is 0.024 mg/m^3,* based on a study submitted by AWPI (#36C: 30000/28C) from the University of Minnesota.

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* Day, May 19, 1982; revised January 25, 1984; and Rispin, 1984.
** Day, December 9, 1983; and Rispin, 1984.
***Zendzian, April 16, 1982; and Rispin, 1984.

PENTACHLOROPHENOL

Comparison of Exposures in Various Situations Without and With Protective Measures
(Summarized from Day, May 19, 1982, revised January 25, 1984; and Rispin, 1984)
(Total Exposure Estimates = Dermal + Inhalation in ug/kg/day)

Exposure Situation	Without Protective Measures		With Protective Measures		Required Protective Measures
	Total Penta exposure/day	Average daily H_xCDD (15 ppm) exposure/ lifetime	Total Penta exposure/day	Average daily H_xCDD (1 ppm) exposure/ lifetime	(Final Regulatory Position)
1. Pressure Treatment Plants					
a. Opening cylinder doors	20 (inhalation)	0.00007 (inhalation)	2.0 (1) (inhalation)	0.0000005 (1) (inhalation)	(1) With gloves (reduce hand dermal exposure 90%) and respirator (reduce inhalation exposure 90%).
b. Entering cylinders*	Not determined	Not determined	(2)	(2)	(2) Protective clothing and respirator reduces dermal exposure by 80% and inhalation exposure by 90%.
c. Bag emptying*	69 to 129	0.0007 to 0.0057	minimal (3a)	minimal (3a)	(3a) Require closed emptying and mixing systems (Assume minimal exposure) or
2. Non-pressure Treatment Plants			7.5 to 19 (3b)	0.000007 to 0.00007 (3b)	(3b) Protective clothing and a respirator
a. Poles/groundline	Not determined	Not determined	(4) Dermal exposure reduced 80%	(4) Dermal exposure reduced 80%	(4) Require gloves and protective clothing

* Information also applies to millwork/plywood applicators and applicators using sodium pentachlorophenate for sapstain control.

PENTACHLOROPHENOL

Comparison of Exposures in Various Situations (cont'd)
Without and With Protective Measures
(Total Exposure Estimates = Dermal + Inhalation in ug/kg/day)

Exposure Situation	Without Protective Measures		With Protective Measures		Required Protective Measures
	Total Penta exposure/day	Average daily H_xCDD (15 ppm) exposure/ lifetime	Total Penta exposure/day	Average daily H_xCDD (1 ppm) exposure/ lifetime	(Final Regulatory Position)
b. Millwork/Plywood					
i) dip/flow	2504	0.0107	254 (5)	0.00007 (5)	(5) Require gloves.
ii) spray	1254* 1300**	0.0054* 0.0055**	129 (6a) 130 (6b)	0.00003* (6a) 0.00004** (6b)	(6) (a) Gloves required. (b) Require gloves, protective clothing and respirator only if visible mist present in the vicinity of the apparatus.
c. Sapstain (sodium) pentachlorophenate)					
i) dip/flow	50	0.0107	5.0	0.00007 (6)	(7) Require gloves.
ii) spray	6.8* 15.1**	0.0011* 0.0011**	2.3* (7a) 1.5** (7b)	0.000007* (8a) 0.000006** (8b)	(8) (a) Require gloves. (b) Require gloves, protective clothing and respirator only if visible mist present in vicinity of spray apparatus.
d. Home and Farm					
i) Brush-on - indoor*** application	2512	0.0001	(11a) Minimal exposure (11b) 251	(11a) Minimal exposure (11b) 0.000001	(11a) Prohibit indoor application. (11b) Allow application with gloves where vapors cannot permeate to interiors. Wear respirators during application if inhalation of vapors cannot be avoided.

* 30 to 40 feet away from the enclosed spray apparatus. (Assume no exposure to HxCDD vapors due to low vapor pressure but assume dermal contact with treatment solutions.)

** In the immediate vicinity of the enclosed spray apparatus. Assume both dermal and inhalation exposure for pentachlorophenol and HxCDD.

*** Exposure estimates assume 6.0 mls solution covering the hands.

PENTACHLOROPHENOL

Comparison of Exposures in Various Situations (cont'd)
Without and With Protective Measures
(Total Exposure Estimates = Dermal + Inhalation in ug/kg/day)

Exposure Situation	Without Protective Measures		With Protective Measures		Required Protective Measures
	Total Penta exposure/day	Average daily H_xCDD (15 ppm) exposure/ lifetime	Total Penta exposure/day	Average daily H_xCDD (1 ppm) exposure/ lifetime	(Final Regulatory Position)
- outdoor application**	2500	0.0001	251(12)	0.000001 (12)	(12) Require gloves.
ii) Spray Application	Not determined	Not determined	(13)	(13)	(13) Require respirator (reduce inhalation exposure 90%) and protective clothing (reduce total dermal exposure 80%)
3. Interior Use of Treated Wood					
a. Occupational End-Use. Poorly Ventilated	0.7 to 3.0 (inhalation)	*	0.1 to 0.4 (9) (inhalation)	(9) *	(9) Prohibit interior use except where necessary. Sealers required.
b. Occupational End-Use. Well Ventilated	0.38 (inhalation)	*	0.06 (10) (inhalation)	(10) *	(10) Prohibit interior use except where necessary. Sealers required.
c. Residential end-use of commercial dip/pressure treated wood	0.8 to 3.0 (inhalation)	*	(14a) 0.11 to 0.48	(14a) *	(14a) Prohibit interior use except where necessary. Require sealers.
			(14b) No exposure	(14b) No exposure	(14b) Prohibit use of non-pressure treated logs for log homes.
d. Residential end-use of treated wood	0.1 to 1.6 (inhalation)	*	(15) 0.01 to 0.23	(15) *	(15) Prohibit interior use except where necessary. Require sealers.

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* It is assumed that HxCDD exposure is negligible, due to its low vapor pressure.

** Exposure estimates assume 6.0 mls solution covering the hands.

INORGANIC ARSENIC

Comparison of Exposures in Various Situations
Without and With Protective Measures (Summarized from Day, May 19, 1982, amended Jan. 25, 1984, and Rispin 1984)

Exposure Situation	Without Protective Measures mg/kg/day	With Protective Measures mg/kg/day	Required Protective Measures (Final Regulatory Position)
1. Pressure Treatment			
a. Ambient air levels*	0.0015 (inhalation)	0.000015 (1)	(1) Require respirators if the arsenic level is unknown or exceeds 10 ug/m^3. (Reduce inhalation exposure 99%.)
b. Opening cylinder doors	Dermal exposure not determined	(2)	(2) Require gloves to reduce hand dermal exposure by 90%.
c. Entering cylinders*	Dermal exposure not determined 0.0015 (inhalation)	Dermal exposure not determined (3a) 0.000015 (inhalation) (3b)	(3a) Require protective clothing. This reduces total dermal exposure by 80%. (3b) Require respirators if the arsenic level is unknown or exceeds 10 ug/m^3.
d. Handling freshly treated wood or mixing dilute solutions	0.0017 (dermal)	0.00017	(4) Require gloves.
e. Bag emptying FCAP**	0.002 (dermal) 0.0015 (inhalation)*	Minimal exposure (5)	(5) Require closed systems.

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* Assume 10 ug/m^3 inorganic arsenic to estimate inhalation exposure (Rispin, April 18, 1984).
** Fluor Chrome Arsenic Phenol

INORGANIC ARSENIC

Comparison of Exposures in Various Situations (cont'd) Without and With Protective Measures

Exposure Situation	Without Protective Measures mg/kg/day	With Protective Measures mg/kg/day	Required Protective Measure (Final Regulatory Position)
2. Non-pressure treatment brush-on applications (outdoors)	0.003 (dermal) (inhalation negligible)	(6) 0.0003	(6) Require gloves and coveralls.
3. Interior uses of wood pressure-treated with inorganic arsenic	0.0000006 (inhalation) (dermal negligible)	7	(7) Allow interior use if wood surfaces are vacuumed.
4. Handling/fabricating treated wood	0.000086 CCA* 0.00021 ACA* 0.000095 CCA** 0.00023 ACA**	0.0000172* (8) 0.000042* (8) 0.000019** (8) 0.00046** (8)	(8) Wear dust masks; reduce inhalation and gastro-intestinal exposure by 80%.

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* Gastrointestinal exposure as a result of inhaling arsenic-laden sawdust particles which become deposited in bronchial passageways, are brought up by ciliary action and then swallowed. (Rispin, April 18, 1984).

** Inhalation exposure as a result of inhaling arsenic-laden sawdust (Rispin, April 18, 1984).

APPENDIX D

Scientific Advisory Panel (SAP) Comments

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

July 15, 1981

MEMORANDUM

SUBJECT: Review of FIFRA Section 6(b)(1) Action on Pentachlorophenol, Inorganic Arsenicals, and Creosote (Wood Preservatives)

FROM: Philip H. Gray, Jr.
Executive Secretary
FIFRA Scientific Advisory Panel (TS-766)
Phil Gray

TO: Deputy Assistant Administrator
for Pesticide Programs (TS-766)

The FIFRA Scientific Advisory Panel has completed review of the Notice of Determination concluding the Rebuttable Presumption Against Registration (RPAR) of pentachlorophenol, inorganic arsenicals and creosote (Wood Preservatives). The review was completed in an open meeting held in Arlington, Virginia, during the period June 17-19, 1981.

Attached is a report of findings by the Panel.

Attachment
Report

cc: Mr. Conlon
Ms. Marcia Williams
Dr. McGrath
Ms. Susan Sherman
Ms. Joan Warshawsky
Ms. Beatty
Mr. Clark
Mr. Smith - USDA
Mr. Ashmore
Panel Members

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

SCIENTIFIC ADVISORY PANEL

Review of Preliminary Notice of Determination Concluding the Rebuttable Presumption Against Registration (RPAR) on Wood Preservative Uses of Pentachlorophenol, Inorganic Arsenicals, and Creosote

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The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel has completed review of plans by the Environmental Protection Agency (EPA) for initiation of regulatory action on pesticide products containing pentachlorophenol, inorganic arsenicals, and creosote under the provisions of Section 6(b)(1) of FIFRA as amended. The review was completed in open meetings held in Arlington, Virginia, during the period June 17-19, 1981. The following Panel members participated in the review: Drs. Torgeson, Davis, Smuckler, Davies, and Metcalf (June 17 and 18).

Maximum public participation was encouraged for the review. Public notice of the meeting was published in the Federal Register on Tuesday, June 2, 1981. In addition, telephone calls were received from and special mailings sent to the general public expressing an interest in activities of the Panel. Written and oral statements were received from the technical staff of the Environmental Protection Agency, from representatives of the American Wood Preservers Institute, Cherokee Industries, Inc., and from several private individuals.

The Panel wishes to express its appreciation to Special Pesticide Review Division and Hazard Evaluation Division staff for their informative briefings. In particular, the Panel wishes to thank Dr. Minnie Sochard for an outstanding scientific briefing on the mutagenicity of the inorganic arsenical compounds. On the other hand, the Panel deplores the lack of scientific objectivity of the presentations by industry concerning biological hazards of wood preservatives, and finds the industry's denial of scientific data concerning the mutagenicity and carcinogenicity of the wood preservatives to be disturbing.

In consideration of all matters brought out during the meeting and careful review of all documents presented by the Agency and other parties, the Panel unanimously submits the following report:*

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* All page numbers in the report refer to the EPA Position Document 2/3

Report of Scientific Advisory Panel Recommendations

The Agency requested the Panel to focus its attention upon a set of issues relating to each of the three wood preservatives (or groups of wood preservatives) under consideration. There follows a list of the issues and the Panel's response thereto:

PENTACHLOROPHENOL

1. In PD-1, margins of safety were calculated based on a no observable effect level (NOEL) of 5.8 mg/kg/day (commercial penta) in a rat teratology study. However, since 5.0 mg/kg/day purified penta produced delayed skull ossification in the same study and this was the lowest dose tested, the Agency stated in the PD-2/3 that no NOEL could be accurately determined. Does the Panel agree that the occurrence of delayed skull ossification indicates an adverse effect which precludes the establishment of a NOEL at that level?

Panel Response:

The Panel believes that one must assume some effect on in utero growth, given the considerable loss of litters in the rat teratology study. Therefore, the Panel agrees that establishment of a No Effect Level (NOEL) at 5.8 mg/kg/day is precluded both by the litter loss phenomenon and by the delayed skull ossification which occurred at the above level in the rat study

2. Although the fetotoxic margin of safety for homeowner application was estimated to be as low as 6 (see p. 357) and the oncogenic risk was estimated to be as low as 1.3×10^{-4} (see p. 364), the Agency did not propose to restrict the sale of over-the-counter products containing 5% or less penta (i.e., ready-to-use penta products). These upper bounds of the risk estimates were based on the assumption that the individual may spill an amount of commercial penta on himself equivalent to the amount that would cover both hands (i.e., 6 ml; see pp. 331-332), a situation that the Agency does not consider likely. Does the Panel believe the Agency is adequately protecting human health by permitting the over-the-counter sales of 5% or less penta to continue?

Panel Response:

The Panel believes that the Agency is adequately protecting human health by permitting the over-the-counter sales of 5% or less penta to continue, provided that the label requires: 1) use of protective clothing, including rubberized gauntlets, goggles and coveralls; and 2) that all uses take place in a well ventilated area.

3. The Agency's estimate of risk to log home residents is currently based on the three measurements of airborne penta in penta-treated log homes (0.77, 0.38, and 0.20 ug/m ^{3}. Although the Agency has proposed the prohibition of future use of penta on the interior surfaces of living quarters, does the Panel have any opinions regarding the need for further exposure studies of log homes?

Panel Response:

The lack of data on human exposure to penta suggests that a more critical review of the fate of penta and its pathways in the environment is badly needed. A full assessment of human urinary excretion of penta, which appears to be widespread in the U.S. population is most important. Additional exposure and epidemiological studies should be conducted. Any future decisions regarding penta should be based on the additional data.

4. The Agency has information suggesting that penta is photolytically converted to hexachlorodibenzo-p-dioxin and hexachlorobenzene. Does the Panel believe the Agency should investigate this subject further in order to adequately assess the risk to individuals exposed to penta-treated wood?

Panel Response:

Yes.

5. On pages 273-274 of PD-2/3, the Agency addresses the role of the wood preserving industry as a source of ambient background levels of penta in the environment. In the absence of data to the contrary, the Agency's commonsense approach assumed that the amount of ambient penta levels contributed by an industry is related to the amount of penta used by that industry. The wood preserving industry uses about 80% of the penta produced in the U.S. Does the Panel agree with this approach? If not, can the Panel suggest a feasible/appropriate method of more accurately addressing the question of the source of environmental penta?

Panel Response:

The Panel believes that it is essentially the Agency's responsibility to develop a method of determining the source of environmental penta. In general, the Agency's reasoning appears to be sound. However, the Panel wishes to stress the need for determining the use(s) of the remaining 20 per cent of the penta produced in the U.S., in order that an accurate exposure assessment can be made.

The Agency also presented the Panel with a set of proposed regulatory actions and modifications relating to penta. These actions are listed below followed by the Panel's recommendation:

1. Require Protective Clothing: Gloves: Panel concurs, with the proviso that elbow length rubberized gauntlets be required, not merely gloves.

2. Require Protective Clothing: Disposable Coveralls: Panel concurs.

3. Require Gloves and Respirators During Spraying (non-pressure) and Opening Cylinder Doors (Pressure Treatment Plants): Panel concurs, with the proviso that coveralls be required as well as gloves and respirators.

4. Require Dust Masks: Not applicable to penta.

5. Require Proper Disposal of Protective Clothing: Panel concurs.

6. Prohibit Eating, Drinking, and Smoking During Application: Panel concurs.

7. Require Closed Systems During Emptying and Mixing Operations: Panel concurs, with the proviso that such systems be recommended for use wherever practicable, rather than required. The Panel believes such a requirement would impose an unfair burden on small operators in terms of additional capital investment, and it encourages the Agency to search for less costly alternatives.

8. Classify for Restricted Use: Panel concurs; however, see also Panel response to Issue #2, page 2.

9. Limit Application of Pesticide or Use of Treated Wood to Outdoors: Panel concurs, but wishes also to express its concern over the problem of disposal of treated wood.

10. Prohibit Uses Likely to Result in Contamination of Food, Feed or Potable Water: Panel concurs.

11. Not applicable to penta.

12. Cancel Spray Application for Homeowner Use: Panel concurs.

13. Require Protective Clothing: Neoprene Suit and Respirator: Panel concurs.

In concluding its review of penta, the Panel wishes to stress two further points: (1) EPA should impose new monitoring requirements in order to establish the sources of penta in the environment; and (2) EPA should require industry to reduce the dioxin content of penta to as low a level as is technologically and economically feasible.

INORGANIC ARSENICALS

There follows a set of issues relating to the inorganic arsenicals posed to the Panel by EPA and the Panel's response thereto:

1. Given that arsenic occurs predominantly in the pentavalent oxidation state in treated wood, problems still remain in the speciation of arsenic in mammals and the environment and in the determination of the effective toxicological agent.

   a) How can analytical problems of determining the species of arsenic in the Taiwanese well-water study be best resolved for risk assessment? (CAG, 1978b)

   b) If pentavalent arsenic is absorbed, will it convert in the body to trivalent arsenic? (pp. 95-101)

Panel response:

The Panel does not believe there is sufficient scientific information to resolve this question at the present time.

2. The estimated oncogenic risks associated with the use of arsenic as a wood preservative are very high. The regulatory options are not correspondingly stringent (Chapter 5). Consequently,

   a) Are the Agency's exposure calculations for workers and consumers realistic? (pp. 195-210)

   b) Is the dermal absorption factor used to estimate human exposure to arsenic from treated wood appropriate? (p. 199)

   c) Is it appropriate to use the Taiwanese study, the smelters study and other epidemiology studies (in which total arsenic levels are used, regardless of oxidation state) to estimate exposure to (pentavalent) arsenic in treated wood? (pps. 214-217)

   d) Are there other factors affecting the oncogenic potency of arsenic in the epidemiology studies on which the risk model is based?

Panel Response:

The Panel chooses not to respond directly to the four parts of Question #2. However, the Panel does believe that with the additional recommendations which it is making in connection with the Agency's proposed regulatory options and modifications, such options and modifications are sufficiently stringent to reduce risk due to arsenic exposure to a satisfactory level.

3. Is additional sampling needed to determine exposure to arsenic in all-weather wood foundations? The Agency is concerned because,

a) Exposure ranges from the National Bureau of Standards (NBS), American Wood Preservers Institute (AWPI), and National Concrete and Masonry studies vary significantly. (p. 189)

b) The air sampling techniques used may not have been appropriate, i.e., air volume of samplers, filter materials, absence of arsine gas measurements.

Panel response:

The Panel does not believe that additional measurements are necessary.

4. Should the Agency reconsider the present teratology and fetotoxicity triggers for the inorganic arsenicals?

Panel response:

The Panel does not believe that the teratology and fetotoxicity triggers need to be reconsidered. However, additional exposure data on the arsenicals is needed, and the Panel encourages EPA to develop and implement monitoring studies to obtain such data.

With regard to the set of proposed regulatory options and modifications for the inorganic arsenicals, the Panel concurs in all the proposed actions applying to both penta and arsenic, with the same provisos as indicated above. With regard to the options pertaining to arsenic alone, the Panel recommends as follows:

4. Require Dust Masks: Panel concurs.

10. Prohibit Uses Likely to Result in Contamination of Food, Feed, or Potable Water (also applicable to penta and creosote)

Following discussion of the apparent need for arsenic treatment of grape stakes, a use EPA has proposed cancelling, the Panel chooses to defer to EPA's judgment on this issue.

11. Reduce Arsenic Surface Residues on Treated Wood

The Panel recommends reducing arsenical residues on treated wood by using clean wood for treatment. The Panel also notes the need for developing a good sealant for outdoor wood treated with arsenic.

CREOSOTE

There follows a set of issues relating to creosote posed to the Panel by EPA and the Panel's response thereto:

1. The Agency determination that creosote is a mutagen is based on consideration of the following issues (see pp. 75-81):

   a) Creosote is a complex mixture exhibiting toxicity as well as mutagenicity: Creosote P1 and P2 are demonstrably toxic in microbial and mammalian test systems.

   b) Responsiveness of the Ames test to the mutagenicity of creosote as well as other complex mixtures.

Does the Panel confirm the bases of our reasoning?

Panel response:

The Panel confirms the basis of the Agency's reasoning.

2. Epidemiology of Creosote - The Agency did not use the Tabershaw and American Association of Railroads surveys (see pp. 49-51) to estimate the oncogenic risk to humans of creosote because of inadequacies of the studies.

   a) Can these human studies be used to substantiate the need for well-conducted epidemiology studies?

   b) Can the information in these studies (i.e., length of employment, age and race distribution, etc.) be used in the design of improved studies?

Panel response:

The Panel recommends that in light of the inadequacies of the above mentioned studies, EPA conduct additional epidemiological studies to obtain the necessary data. The data in the Tabershaw and AAR studies can be used in the design of improved studies.

3. The Agency performed a qualitative evaluation, rather than a quantitative risk assessment, for oncogenicity of creosote (see pp. 85-94) because of the variable composition of creosote due to source and industrial preparation, synergism among its chemical components, insufficient exposure information and lack of an appropriate epidemiology study for direct estimation of human risks. Does the Panel advise the Agency to ask for:

a) Rodent inhalation studies using creosote aerosols?

b) Epidemiology studies of wood preservative treatment plant workers?

c) More extensive exposure studies in wood preservative pressure treatment plants in which creosote vapor and polycyclic particulate organic matter (PPOM) are sampled quantitatively and qualitatively (the latter to identify chemical profiles of airborne material)?

Panel response:

The Panel believes there is enough rodent data available on creosote. However, it does recommend additional epidemological studies of wood preservative treatment plant workers and more extensive exposure studies in such plants.

4. It has been brought to the Agency's attention that some creosote is used in commercial non-pressure operations. Does the Panel advise that the Agency seek exposure data for estimation of hazard to workers in non-pressure treatment plants?

Panel response:

The Panel believes it logical that EPA seek such information.

5. Creosote for home and farm use, railroad tie repair, and groundline treatment of poles is being proposed as restricted to certified applicators only. In light of the lack of exposure data, other than isolated case studies, does the Panel think this restriction is justified?

Panel response:

The Panel believes the certified applicator requirement justified except in the case of farm use where it appears to be too restrictive. The Panel suggests the Agency examine ways to alleviate this situation.

With regard to the Agency's proposed regulatory options and modifications pertaining to creosote, the Panel concurs in all of the Agency's recommendations with one exception. As indicated above, the Panel believes it unfair to small farmers to require them to seek certification in order to use creosote and recommends that ways be found of enabling farmers to use this compound without becoming certified.

The Panel also recommends that EPA examine further the possible use of sealants in connection with indoor uses of creosote, some of which the industry claims are essential.

FOR THE CHAIRMAN

Certified as an accurate report of Findings:

Philip H. Gray, Jr.
Executive Secretary
FIFRA Scientific Advisory Panel

Date: July 15, 1981

APPENDIX E

United States Department of Agriculture (USDA) Comments

United States
Department of
Agriculture

Office of
Environmental
Quality

Washington,
D.C.
20250

May 29, 1981

RECEIVED

JUN 18 1981

Office of the Assistant Administrator
For Pesticides and Toxic Substances

Honorable Anne M. Gorsuch
Administrator
U. S. Environmental Protection Agency
Washingtgn, D. C. 20460

Dear Ms. Gorsuch:

This is the U. S. Department of Agriculture's response to the U. S. Environmental Protection Agency's (EPA) Preliminary Notice of Determination concluding the Rebuttable Presumption Against Registration (RPAR) of the wood preservative uses of pesticide products containing creosote, inorganic arsenicals, and pentachlorophenol.

We concur with the decisions to cancel the spray method of application of products containing five percent or less pentachlorophenol, and to continue the registrations of the other wood preservative uses of creosote, pentachlorophenol, and the inorganic arsenicals. We have identified several problems with the proposed modifications in the terms and conditions of the registrations. Our specific comments are contained in the enclosure which is an integral part of this response.

We believe EPA has underestimated the economic impacts that could result if specific uses of the wood preservatives were cancelled or restricted. There are no indications that EPA has taken into account data that was included in Chapter 8 of the USDA-States-EPA Assessment Team Report transmitted to the agency on November 4, 1980. For example, EPA apparently did not consider economic impacts to local communities, omitted the costs of converting treatment plants from use of arsenicals to either creosote or pentachlorophenol, only considered first-year impacts for certain uses, and underestimated the use of untreated wood as a substitute for treated sills, plates and structural framing.

We agree that more data are needed on applicator exposure, disposal of treated wood, and residue levels of the wood preservatives in water, air, and food or feed that result from the uses of these products. The Department is currently involved in studies on migration of creosote in soil and water, determination of levels of wood preservatives in the air around or in treated wood structures, development of methods to reduce vaporization and surface residues, quantification of applicator exposure, and the determination of inorganic arsenic in food crops. We are willing to cooperate with EPA and industry in considering the need for additional data or studies as necessary.

Sincerely,

BARRY R. FLAMM
Director

2 Enclosures

Secretary of Agriculture's
Specific Comments to
the Wood Preservatives Notice of Determination PD 2/3

We agree with the recommended label modifications requiring protective clothing and equipment with one exception. The use of half-mask canister or cartridge respirator is not necessary when entering arsenical pressure treatment cylinders. Since these wood preservatives are inorganic salts which have no measurable vapor pressure, there are no fumes that need to be trapped. A dust mask which would prevent inhalation of arsenate particles or mist would be sufficient.

Clarification is needed regarding the requirements for protective clothing for certified and noncertified applicators of creosote and pentachlorophenol for home and farm uses. For applications of creosote, or pentachlorophenol concentrations of greater than 5 percent, no differentiation in clothing requirements should exist; that is, both certified and noncertified applicators (who may be applying the chemical under the supervision of a certified applicator) should wear the same protective clothing. Once pentachlorophenol is diluted to 5 percent or less, or in the case of products sold in a 5 percent or less formulations, long-sleeved shirts and trousers offer adequate protection.

The use of wood preservatives for industrial uses should be restricted where the worker has the risk of exposure on a daily basis. However, the restrictions on homeowner use and on those contractors doing construction work for the homeowner appear to be extreme given the limited risk of exposure for persons in these categories. For example, classifying the brush-on use of inorganic arsenicals as restricted-use pesticides would mean that carpenters who want to treat the end cuts during fabrication of a structure must be certified pesticide applicators. We are also concerned that the proposed restricted-use classification will require certification of entirely new groups of workers who do not fit into the classification of commercial forestry, or farm-oriented certified applicators. We question whether current certification programs apply to these new groups.

The proposed statements prohibiting the application of creosote, pentachlorophenol, or inorganic arsenicals to wood which is intended for interior, except for those support structures which are in contact with soil in barns, stables, similar sites and all weather wood foundations, sills and plates, may cancel some uses for which there are no substitutes. Exposure can be reduced for many of these uses, such as sealing creosote treated woodblock flooring beneath a pitch wearing surface. Another important use is that of penta treated wood for laminated timbers for warehouses, indoor swimming pools, and other buildings where the type of use creates a high decay hazard. Other preservatives are not practical. Creosote is an unsuitable preservative for esthetic reasons and arsenicals interfere with gluing. Recent research has shown that the exposure from the use of penta in enclosures is small, generally less than 1 microgram per cubic meter which can be reduced by 80 to 90 percent by coatings or by surface treatments that convert the penta to chemicals with essentially zero vapor pressure. (We are enclosing a research paper about clear coatings.) A solution formulated for the latter use is now commercially available. We believe such formulations can be used safely, and these specialty uses should not be limited where exposure can be effectively reduced.

The precautionary statements proposed in the Position Document which prohibit the application of the inorganic arsenicals, creosote, or pentachlorophenol to wood which will be used in a manner which may result in direct exposure to domestic animals or livestock, or in the contamination of food, feed, or drinking and irrigation water (e.g., food crates, irrigation flumes, vegetable stakes, feedlot bins and watering troughs), could prohibit virtually all agricultural uses of treated wood (such as fence posts, gates, cattle guards, supports for feed bunks, retaining walls, etc.) since it can be argued that any of these uses could result in direct animal contact. A strict interpretation of these restrictions could also prohibit the use of treated wood in the construction of bridges or docks because in many cases treated timbers are in direct contact with surface water or the subsurface water table. Although more data are needed on residue levels of the wood preservatives that result from such uses, available data in the USDA-States-EPA Assessment Report does not support the contention that these uses will result in significant exposure to the general public. A case in point is the use of arsenical treated wood for vegetable stakes and grape stakes, watering troughs, and feed bunks. If "visibly clean" treated wood which contains not more than 0.1 mg. of soluble arsenic per 100 cm^2, and if it is assumed that all available arsenic is solubilized in the initial fill of a watering trough 2 feet X 2 feet X 6 feet, the arsenic content in that water would not exceed the maximum drinking water standards for humans as established by the Department of Health, Education, and Welfare in 1962. A strong data base (see Chapter 10, Report of the USDA-States-EPA Preservative Assessment Team) supports the thesis that contact of plants with arsenates does not increase the arsenic content of these plants.

While no food tolerances have been set specifically for the wood preservative pesticides, there are tolerances for arsenic residues on a wide variety of food crops. Normal residue levels for any crop could be used as the tolerance level for that crop to insure that no increase in residue resulted from the use of treated wood. The fact that "clean" salt pressure treated wood would have essentially no residue which could be picked up by a food crop must be taken into account, especially when considering the fact that crops grow in a soil environment containing 2 to 5 parts per million arsenic and that plants contain arsenic as a natural component of the fruit, leaf, or root. The use of arsenic as a plant growth regulator in grapefruit production and the long-term use of arsenical treated wood for vegetable and grape stakes--both without any increase in arsenic levels of the produce--are also strong arguments that the restrictions proposed for arsenical treated wood for agricultural uses (greenhouses, mushroom flats, support stakes for vegetables and grapes, etc.) are inappropriate.

The proposed label requirement that in-line filters must be used with arsenical preservatives may not achieve the desired result of limiting surface deposits of arsenical preservatives unless the filters are properly maintained. The requirement that a post impregnation vacuum be applied is poor technology, at least in the case of chromated copper arsenate (CCA) preservatives, since this practice will introduce wood sugars into the treating solutions and result in sludging of CCA solids in storage and working tanks, thus aggravating the very problem the requirement is intended to solve. A simple label requirement that arsenical treated wood must be visibly clean would achieve the result desired and would not place EPA in the position of dictating treatment methodology and fixing the state-of-the-art. The post-treatment rinsing to remove surface residues could be made mandatory for wood to be used in food contact applications. However, the water used to wash the wood would have to be collected, stored, and disposed of as a hazardous waste. Since few waste disposal sites will take arsenic wastes, this process would greatly add to the cost of wood treatment and add to the already critical waste disposal problem. We believe it would be preferable to set concentration or residue standards and let industry meet the standard in ways that best suit their specific situations.

The proposed requirement that treated wood either be disposed of by onsite burial, or that if the pesticide-treated wood wastes exceed 1,000 kilograms per site, disposal must comply with the provisions of the Resource Conservation and Recovery Act, as amended, will result in significant costs contrary to EPA's expectation. There are over 4,000 bridges on National Forest System lands which utilize treated timber piles, posts, and planks as bridge components. The total weight of each bridge would exceed 1,000 kg in about every case. Unusable materials from these bridges are often burned when the bridges are replaced. The cost of dismantling, hauling, and disposing of this material in approved disposal sites will be significant. Such added costs would adversely impact the cost of road construction which ultimately affects our ability to manage the forest resources. We believe such requirements are premature because EPA admits that the hazards of current disposal methods have not been quantified. We are willing to work with the EPA in the development of scientific data designed to evaluate workable disposal methods.

We are also concerned with the proposal to require labels under the Toxic Substances Control Act (TSCA) requiring impervious gloves to be worn by all who handle preservative treated wood, and requiring individuals who saw pesticide treated wood to wear protective clothing and a dust mask. We feel these regulations involve unrealistic and unenforceable restrictions.